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Self-Warmth, Self-Coldness and Self-Esteem as Predictors of Quality of Life and Disability in Chronic Pain

A systematic review of the impact of fibromyalgia on quality of life using the Short Form-36 and an empirical study of the relationship between self-warmth, self-coldness and self-esteem on quality of life and disability in a chronic pain population

Caitríona Doughty

Doctorate in Clinical Psychology

The University of Edinburgh

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DClinPsychol Declaration of Own Work

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List of Abbreviations

FM- Fibromyalgia

HC- Healthy Control

HRQoL- Health Related Quality of Life

SF-36- Short Form 36

PF-Physical Functioning

PR- Physical Role

BP- Bodily Pain

GH- General Health

VT- Vitality

ER- Emotional Role

SF- Social Functioning

MH- Mental Health

CI- Confidence Interval

MCS- Mental Component Summary

PCS- Physical Component Summary

BMI- Body Mass Index

ACR- American College of Rheumatology

SCS- Self-Compassion Scale

BPI-SF- Brief Pain Inventory- Short Form

RSES- Rosenberg Self-Esteem Scale

HADS- Hospital Anxiety and Depression Scale

PDQ- Physical Disability Questionnaire

FAS-Fibromyalgia Assessment Status

FIQ- Fibromyalgia Impact Questionnaire

VAS- Visual Analogue Scale

QOL-Quality of Life

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Full Thesis Abstract

Background: Chronic pain conditions particularly fibromyalgia (FM) are an important issue considering the demand that they place on health services and the negative impact on an individual's well-being. Research regarding what impact FM may have on the various domains of health related quality of life is sparse. In addition, research identifying predictors relating to a person's self-concept on pain outcomes such as quality of life and disability is scarce in a chronic pain population. Self-esteem has been linked to psychological adjustment in various chronic diseases (Chong et al, 2009) and is suspected to be a vulnerability factor in FM (Johnson et al., 1997; Michielsen et al., 2006). Research on self-compassion found that it is a significant predictor of increased psychological adjustment in people with chronic medical conditions (Wren, Somers, & Wright, 2011). The majority of research on self-compassion has been conducted in non-clinical samples. Identifying the predictive values of self-esteem and the self-compassion subscales (self-warmth and self-coldness) in relation to pain outcomes are useful provided they can be enhanced and utilised to inform intervention.

Aims: This research portfolio had two aims, to systematically review and carry out a meta-analysis with the literature investigating the impact of FM on health related quality of life using the Short Form-36 version one and to investigate whether self-warmth, self-coldness and self-esteem act as predictors of quality of life and disability for individuals with chronic pain.

Method: A systematic review and meta-analysis of studies which assessed the impact of FM on health related quality of life was undertaken. Sensitivity and subgroup analyses were conducted to address the level of heterogeneity in the studies. The empirical study comprised of a cross-sectional design in which 60 individuals with chronic pain were recruited from three NHS sites based in Fife and Lothian and a pain self-management group in Fife to complete six validated psychometric questionnaires: Self Compassion Scale (Neff, 2003), Rosenberg Self-Esteem Scale (Rosenberg, 1965), Brief Pain Inventory-Short Form (Cleeland, 1991), Pain Disability Questionnaire (Anagnostis, Gatchel, & Mayer, 2004), Hospital Anxiety and Depression Scale (Zigmond and Snaith, 1983) and Quality of Life Scale (Burckhardt, Woods, Schultz, & Ziebarth, 2003).

Systematic Review Results: In total, 18 studies met the inclusion criteria of the systematic review and demonstrated that the health related quality of life of individuals with FM was lower compared to healthy controls on all eight subdomains of the SF-36 particularly Physical Role. It was found that Social Functioning was the subdomain least affected when comparing participants with FM to healthy controls.

Empirical Project Results: Quality of life was lower than previous research with females reporting a higher level of quality of life than males. It was found that after controlling for demographic and clinical variables, self-warmth was the only significant predictor for quality of life but not on levels of disability. Neither self-coldness nor self-esteem were significant predictors on scores of quality of life or disability.

Conclusion: The above studies expand literature on the nature of chronic pain and its outcomes such as health related quality of life. The meta-analysis evidenced that HRQoL was lower in individuals with FM than in healthy controls. The association between symptom severity and quality of life requires further investigation in FM.

Psychological interventions targeting the development of self-warmth attributes and skills may have a beneficial effect in improving quality of life for people with chronic pain. While the systematic review highlighted that FM has a more significant impact physically rather than mentally in relation to quality of life, both studies highlighted the need for interventions to target the psychological adjustment of people with chronic pain conditions.

Lay Summary of Thesis

This thesis consists of two papers. The first paper looks at the effect that fibromyalgia has on people's quality of life. Fibromyalgia is a long term condition that causes pain all over the body. Quality of life was measured by a questionnaire called the Short-Form-36. This questionnaire focuses on eight different areas of quality of life known as subdomains regarding ability to carrying out physical activities, general health, pain, mental well-being, ability to interact socially, and energy levels. The first paper looked at 18 studies which compared the scores of the SF-36 subdomains for people with fibromyalgia to people who do not have any pain conditions. People who do not have any pain condition are referred to as healthy controls in the present study. This study combined all scores of the 18 studies for the SF-36 subdomains together to get an average score in order to see which one would be most affected in people with fibromyalgia compared to healthy controls. It was found that people with fibromyalgia reported poorer quality of life than healthy controls particularly in relation to their physical ability to carry out activities. Ability to interact socially was least affected in people with fibromyalgia compared to healthy controls. Overall it was concluded that people with fibromyalgia are not all similar with regards to levels of quality of life and reasons for this should be explored further in future research. The second paper in this thesis focuses on people with chronic pain, which means that they have had continuous pain for at least three months. This paper aimed to answer whether an individual's sense of worth (self-esteem) or an ability to be kind to oneself (self-warmth) or judgemental to oneself (self-coldness) in times of difficulty predicted pain outcomes in relation to their levels of quality of life and level of disability. Sixty Individuals with chronic pain completed six questionnaires which asked questions relating to their severity of pain, mood, quality of life, disability, self-esteem, self-warmth and self-coldness. It was found after carrying out statistical analysis that people with higher levels of self-warmth regardless of mood or pain had better levels of quality of life but it did not affect levels of disability. However, self-coldness and self-esteem did not predict better or poorer levels of quality of life or disability. From the results of this study, it was suggested that psychological interventions should be aimed at helping to increase people's self-warmth in order to improve levels of quality of life.

Journal Article 1

The impact of fibromyalgia on health related quality of life using the Short-Form 36: A systematic review and meta-analysis

Authors

Caitríona Doughty, Dr. Laura Keith, Dr. Paul G. Morris, & Dr. Nuno Ferreira

Affiliations

Department of Clinical Psychology NHS Fife, Clinical and Health Psychology, University of Edinburgh Scotland.

Corresponding Author

Caitríona Doughty, Clinical Psychology Department, Lynebank Hospital, Halbeath Road, Dunfermline, Fife, KY11 4UW

Written in accordance with the instructions for 'Journal of Contextual Behavioural Science' (see Appendix A for author guidelines)

Abstract

Objective: To systematically review the literature to identify the impact of fibromyalgia (FM) on individuals with fibromyalgia in comparison to aged matched healthy controls on specific aspects of health related quality of life (HRQoL) using the Medical Outcomes Study Short-Form-36 (SF-36).

Methods: Multiple electronic databases were searched for studies reporting SF-36 subdomain mean and standard deviation scores for people with FM and healthy controls. Studies were methodologically appraised using a specifically developed quality criteria tool. A random-effects meta-analysis was performed to address the review questions.

Results: In total, 18 studies were eligible for inclusion in the meta-analysis, reporting on 1733 individuals with FM and 3468 healthy controls. Meta-analyses found that the subdomain Physical Role was the most severely effected in individuals with FM compared with Healthy Controls. The least affected subdomain was found to be Social Functioning (SF). It was calculated that the meta-analysed pooled mean HRQol score for the SF-36 physical component summary score was 38.81 (95% CI: 31.2-46.4) and mental component summary score was 42.3 (95% CI: 34.3-50.2). Sensitivity analyses in relation to the methodology quality criteria did not significantly reduce heterogeneity in the review. Subgroup analysis did find a reduction in heterogeneity in relation to geographical area.

Conclusions: Individuals with FM have lower levels of HRQoL than healthy controls. This review supports that FM seems to have a greater negative impact on physical rather than on mental component summary scores of HRQoL though both are substantially affected.

1.1 Introduction

Fibromyalgia (FM) is a chronic pain disorder that affects 2-3% of the general population and is more prevalent in middle aged women (Quieroz, 2013). The prevalence of fibromyalgia can vary depending on different countries (Branco, Bannwart, Failde et al., 2010). Similarly, the particular characteristics and symptoms reported by individuals with fibromyalgia may differ depending on geographical regions which has been found among patients with chronic widespread musculoskeletal pain (McBeth & Jones, 2006). The American College of Rheumatology (ACR; 1990) developed criteria to classify FM for research, which included the presence of chronic widespread pain in combination with tenderness on examination at 11 or more 18 anatomical sites known as tender points. In 2010, the ACR introduced new preliminary diagnostic criteria which no longer requires tender point examination. Although FM is characterised by widespread pain, other symptoms include fatigue, sleep disturbance, morning stiffness, headaches and depressive mood (Wolfe, Clauw & Fitzcharles, 2010). The aetiology of FM is unknown, although it is generally considered a central sensitization syndrome (Clauw, 2014). This refers to the theory that the central nervous system may amplify sensory input across various organ systems resulting in a heightened sense of pain in a number of areas e.g. headaches, irritable bowels, tender points (Woolf, 2010). There is no known cure for FM, therefore, treatment is focused on preserving or improving daily function and alleviating pain (Albin, Fitzcharles, & Buskila, 2013).

FM has diverse effects on health-related quality of life (HRQoL), both physically and mentally (Hoffman & Dukes, 2008). Various terms have been used interchangeably with HRQoL including functional status, health status, and quality of life (Van Son, De Vries, Roukema, & Den Oudsten, 2013). An international group of researchers suggest that there are six fundamental domains of HRQOL: physical functioning, psychological functioning, social functioning, role activities, overall life satisfaction and perceptions of health status (Berzon, Hays, & Schumaker, 1993). While the objective dimensions aim to define a patient's degree of health, the individual's subjective evaluation serves to translate the health status into the actual quality of life experienced. Evaluating HRQOL

can be useful in that reduced HRQoL in FM is associated with increased use of healthcare resources (Kim, Kim, & Lee, 2012), poor prognosis of treatment (Torre, Martin-Corral, & Callejo, 2008) and increased levels of depression (Soriano-Maldonado, Amris, & Ortega, 2015). Therefore, decreasing the adverse impact of FM on HRQoL should be a key focus for informing treatment development.

The Medical Outcome Study 36-item Short Form Health Survey (SF-36) is one of the most widely used tools for assessing HRQoL (Garratt, Ruta, Abdalla, Buckinghamm & Russsell, 1993). It defines HRQoL as the degree to which physical health affects an individual's perceived functioning and well-being in relation to psychological, social and physical aspects of life (Ware & Sherbourne, 1992). The SF-36 is organised into eight subscales that evaluates: physical functioning (PF), physical role (PR), bodily pain (BP), general health (GH), vitality (VT), emotional role (ER), social functioning (SF) and mental health (MH). Scores on these subscales can be combined to form two higher-order summary scores, the Physical Component Summary (PCS) and Mental Component Summary (MCS). The PCS is calculated by positively weighting the four subscales in the physical domain (PF, PR, BP and GH) and the remaining mental domain subscales (VT, SF, ER, MH) negatively. In contrast the MCS is calculated by positively weighting the four mental domain subscales and negatively weighting the four physical domain subscales. This measure has been found to be a reliable and a valid measure in FM (Timmerman, Calfa, & Stuifbergen, 2013), correlating well with disease-specific measures like the Fibromyalgia Impact Questionnaire-Revised (FIQ-R; Bennett, Friend, & Jones, 2009) and the Fibromyalgia Assessment Questionnaire (FAS; Salaffi, Sarzi-Puttini, & Girolimetti, 2009). Research suggests that the SF-36 is a useful generic measure which can compare HRQoL between populations rather than providing a disease specific assessment such as the FIQ and the FAS.

Increased levels of pain, physical disability, and mood disorders (anxiety and depression) have been associated with reduced quality of HRQoL for individuals with FM (Campos, 2012). Studies suggest that several factors may affect HRQoL in individuals with chronic pain, such as gender, age, body mass index (BMI), disease severity, and duration of disease (Moradkhani, Beckman, & Tabibian, 2013; Faust, Halpern, Danoff-Burg, & Cross, 2012). To date there have been a limited number of systematic reviews looking at the

impact of FM on HRQoL. Hoffman et al. (2008) has been the most recent systematic review which looked at health related quality of life in people with fibromyalgia compared to that of people in the general population and people with other long term conditions using the SF-36 and SF-12. While Hoffman's (2008) review found that individuals with FM had significant impairments in both mental and physical health domains in comparison to the general population and individuals with specific pain conditions, it did not focus on the eight components of the SF-36 or the two higher order summary scores. Therefore, the present study will be the first to carry out a meta-analysis examining which specific components of the SF-36 are most effected for individuals with FM. Such information can highlight the specific areas where individuals with FM experience particular difficulty and allow healthcare providers to develop interventions for these specific difficulties.

1.1.1 Aims of the Research:

1. Systematically review the literature appraising the impact of FM on the eight subdomains of the SF-36 by providing a pooled meta-analysed mean score for each subdomain of the SF-36.
2. To compare scores of individuals with FM on the SF-36 with aged matched healthy controls by providing a pooled meta-analysed mean difference score for each subdomain.
3. To compare both meta-analysed pooled mean scores of Physical Component Scores (PCS) and Mental Component Scores (MCS) for individuals with FM to determine which is more severely affected by FM.
4. To compare scores of individuals with FM on the PCS and MCS with aged matched healthy controls.

1.2 Materials and Methods

1.2.1 Search Strategy

In order to identify eligible studies, systematic searches of the following databases were conducted: Web of Science Core Collection, Ovid (incorporating EMBASE Classic and

Embase 1947 to 2015 October 07, Psych Info 1806 to October Week 1 2015, Ovid Medline In-Process and Other Non-Indexed Citations and Ovid Medline (R) 1946 to Present) and EBSCOHost (incorporating CINAHLPlus and ERIC) online databases. Search terms were developed (Table 1.1) with reference to common key words and were searched for within titles, keywords, abstracts. Since the SF-36 was developed in 1992, the search was restricted from January 1992 to October 2015. Following search completion, titles and abstracts were initially screened to eliminate studies not meeting the inclusion criteria. The remaining studies were read in full to determine appropriateness for inclusion.

Table 1.1 Electronic Database Search Terms

Electronic Database Search Term	
(1)	Fibromyalgia
(2)	Health Related Quality of Life
(3)	Quality of Life
(4)	Health Status
(5)	HRQoL
(6)	QoL
(7)	Short Form 36
(8)	SF-36
(9)	SF36
(10)	(2) or (3) or (4) or (5) or (6)
(11)	(1) and (10)
(12)	(7) or (8) or (9)
(13)	(11) and (12)

1.2.2 Selection Criteria

Studies were eligible for selection if they used quantitative methods and analysis, which focused on adult samples (defined as age > 18 years) with a diagnosis of FM based on either the 1990 or 2010 published classification criteria by the American College of Rheumatology (ACR). The review also required that the studies used the SF-36 version 1 to assess HRQoL rather than the SF-36 version 2 as they have different scoring systems which limits the comparability of the scores. While SF-36 version 2 has shown improvement over accuracy, reliability and validity compared to version 1, many studies in relation to rheumatic disorders and FM continue to use version 1 (Matcham, Scott, & Raynor, 2014; Wolfe, Michaud, Li, &

Katz, 2010). In order to reduce publication bias, grey material including academic, doctoral and masters' dissertations and other unpublished papers were included. Non empirical work such as book chapters or reviews were excluded. Addressing the review question involved including only case-controlled studies so that the HRQoL subdomain scores could be compared between individuals with FM and the general population. Theoretical or review studies were excluded.

1.2.3 Data Extraction and Quality Assessment

It is important to evaluate the methodological quality of studies in the systematic review so that the reliability and validity of the result can be predicted (Jarde, Losilla & Vives, 2013). Available tools for evaluating methodological quality are predominantly developed to evaluate treatment effectiveness using a randomised controlled trial design e.g. the Centre for Reviews and Dissemination (CRD, 2008). As the eligible studies in this review are observational studies, such checklists would not be compatible. While reporting on quality of observational studies has increased in recent times (Mallen, Peat, Croft, 2006) systematic reviews on quality assessment tools for evaluating observational studies have concluded that no single tool has been found to be reliable (Sanderson, Tatt, & Higgins, 2007). The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE; Vandenbroucke, von Elm, Altman, et al, 2007; vonElm, Altman, Egger et al, 2007) is supported by the Cochrane Collaboration and contains a checklist of recommendations of items to be included in reports of observational studies in epidemiology. However, it was not designed to evaluate methodological quality, therefore, for this review an assessment tool was developed and adapted from a number of sources including the STROBE (Kmet, Lee, & Cook,2004), York's Centre for Reviews and Dissemination guidance for undertaking reviews in healthcare (CRD, 2008) and Scottish Intercollegiate Guidelines Network (SIGN, 2008). The final assessment tool (Appendix B) has a total of five quality criteria which include the domains of selection bias, statistical power, measure validity and method of analysis. Four categories were arbitrarily established for quality assessment: 'yes=2', 'partial=1', and 'no or not applicable=0'. In keeping with the guidance of the CRD (2008), a total numerical score was not calculated for the quality of each paper (Juni, Witschi, Bloch, & Egger, 1999). All studies were rated according to the quality criteria by the author and two independent raters. Reliability was good with a Krippendorff's alpha of .7 (Hayes & Krippendorff, 2007).

Discrepancies were resolved through discussion and re-examination of the studies. The quality ratings assigned for each paper are summarised in Table 1.2. In an attempt to retrieve missing or incomplete data particularly MCS and PCS scores, emails were sent to all authors of the studies that were included in this review.

1.2.4 Statistical Analysis

The eight subdomain scores of the SF-36 for individuals with FM and control groups in each study were extracted as mean totals and mean differences (MD) ±SD. In addition, pooled means for PCS and MCS scores in the FM sample were meta-analysed for six of the studies that reported these values. Mean differences for the PCS and MCS were calculated and compared within the group of individuals with FM to determine whether there was a significant difference between the two components in this group. The PCS and MCS scores were also compared between individuals with FM and the healthy controls using mean totals and standard deviations. The OpenMeta-Analyst (Wallace, Dahabreh, Trikalinos et al., 2012) programme calculated scores in all studies eligible for the meta-analysis with 95% confidence intervals and combined by using random effects model (DerSimonian-Laird random effects method). Heterogeneity was assessed using the value of I^2, whereby 25%, 50% and 75% indicated low, moderate and high heterogeneity respectively (Higgins, Thompson, Deeks, & Altman, 2003). Heterogeneity was found to be high between studies, therefore sensitivity and subgroup analyses were conducted.

1.3 Results

1.3.1 Search Results

Electronic databases were searched on 7th October 2015, with a return of 986 studies. Following removal of duplicates, there were 633 studies. First, titles of articles were screened resulting in the exclusion of 183 studies. Secondly, abstracts were reviewed and 341 were removed due to not meeting eligibility criteria for inclusion. Reference lists of all 109 studies that met the inclusion criteria were read in full. The 91 studies that were excluded at this stage are outlined in Appendix C. Eighteen studies were identified that met the inclusion criteria and were deemed appropriate to be part of the final methodological review and

analysis. This process is summarised in Figure 1.1 by a flowchart based on the PRISMA statement.

1.3.2 Characteristics of Included Studies

Table 1.3 provides a summary of descriptive characteristics and key findings of the 18 studies included in this systematic review. The included studies were all case-controlled cross-sectional studies published between 2000 and 2015. All studies included in the review used the 1990 American College of Rheumatology. Studies differed by country of origin and used translated versions of the SF-36 including Turkish (Akkaya et al., 2012; Alanoglu et al., 2005; Batmaz et al., 2013; Birtane et al., 2007; Tander et al., 2008; Turkyilmaz et al, 2012; Tuzun et al., 2004), Portuguese (Avila et al., 2014; Cardoso et al., 2011; Pagano et al, 2004), Spanish (Carillo et al, 2015; Segura-Jimenez et al., 2015), Italian (Salaffi et al., 2009), Hebrew (Neumann et al., 2000), Persian (Kolahi et al., 2010; Roshan et al., 2008) and Swedish (Andrell et al., 2014).

1.3.3 Methodological Quality Assessment

The methodological quality scores for each paper are provided in Table 1.2 According to the quality assessment tool, the majority of the studies included were of good methodological quality scoring highly across all criteria apart from the power/sample size. Ten studies were considered to be under-power (Alangolu et al., 2005, Avila et al. 2014, Batmaz et al., 2013, Birtane et al., 2007, Cardoso et al., 2011, Pagano et al., 2004, Smith et al., 2010, Tander et al., 2008, Turkyilmaz et al., 2012, & Tuzun et al., 2004).

1.3.4 Sample characteristics

There was marked variation in sample sizes with the number of individuals with FM ranging from 16 (Cardoso et al., 2011) to 459 (Segura-Jimenez et al, 2015). There was a total of 1733 individuals with FM included in this review. The control group in this review had a sample size ranging from 16 (Cardoso et al., 2011) to 1579 (Salaffi et al., 2009), comprising of 3468 in total. It was found that 15 studies recruited only females with FM, two studies included males with FM (Avila et al., 2014; Salaffi et al., 2009) and one study only included males with FM (Batmaz et al., 2013). The mean age of participants in the reviewed studies were 46 years for both groups, however seven studies only provided a total age score for both groups

(Akkaya et al., 2012; Alanoglu et al., 2005; Andrell et al., 2014; Avila et al., 2014; Batmaz et al., 2013; Birtane et al., 2007; Smith et al., 2010). Overall studies tended not to include individuals over the age of 65. Five studies specified age restrictions such as 35-60 (Cardoso et al., 2011; Pagano et al., 2004; Roshan et al., 2008, Segura-Jimenez et al., 2015., Smith et al., 2010), however only one of these studies (Roshan et al., 2008) explored age as a confounding variable in relation to HRQoL.

The majority of studies also had a trained health professional confirm the FM diagnosis rather than relying solely on self-report measures. Symptom severity of FM was measured using various psychometric measures in the reviewed studies. The Fibromyalgia Impact Questionnaire (FIQ) was administered in seven of the studies (Akkaya et al., 2012; Avila et al. 2014, Birtane et al. 2007, Carrillo et al. 2011, Pagano et al. 2004, Tander et al. 2008, and Turkyilmaz et al. 2012), the Fibromyalgia Impact Questionnaire-Revised in one study (Segura et al., 2015) whereas a Visual Analogue Scale, tender point count and less well defined yes/no checklist of chronic symptoms were used in the remaining studies. Additionally, given the variation in measures used, the specific symptoms investigated within each of the individual studies also varied as did the intensity of the symptoms presented.

1.3.5 Settings

Individuals with FM were recruited from outpatient clinics and FM associations. Two of the studies included in the review used general population-based samples rather than healthcare settings (Salaffi et al. 2009; Smith et al., 2010). A benefit of using a general population sample was that results were not biased by help-seeking (Mas, Carmona, Valverde, 2008).

1.3.6 Statistical Analysis

A variety of statistical analyses were conducted across studies and ten of the studies had normally distributed data. T-tests and analyses of variance were the prominent statistical techniques to examine the difference between individuals with FM and healthy controls in relation to the SF-36 sub-domains. Four studies were awarded “yes” and fourteen received “partial” in relation to appropriate use of statistics. The studies that were awarded “yes” reported confidence intervals and effect sizes. Reporting of demographic information was variable. Some studies noted significant differences between individuals with FM and healthy controls in relation to education level, BMI and employment which were not accounted for

in their analysis of SF-36 scores (Kolahi et al, 2010; Pagano et al. 2004). In order to explain the level of heterogeneity found, sensitivity analysis was conducted.

Figure 1.1 Search Process

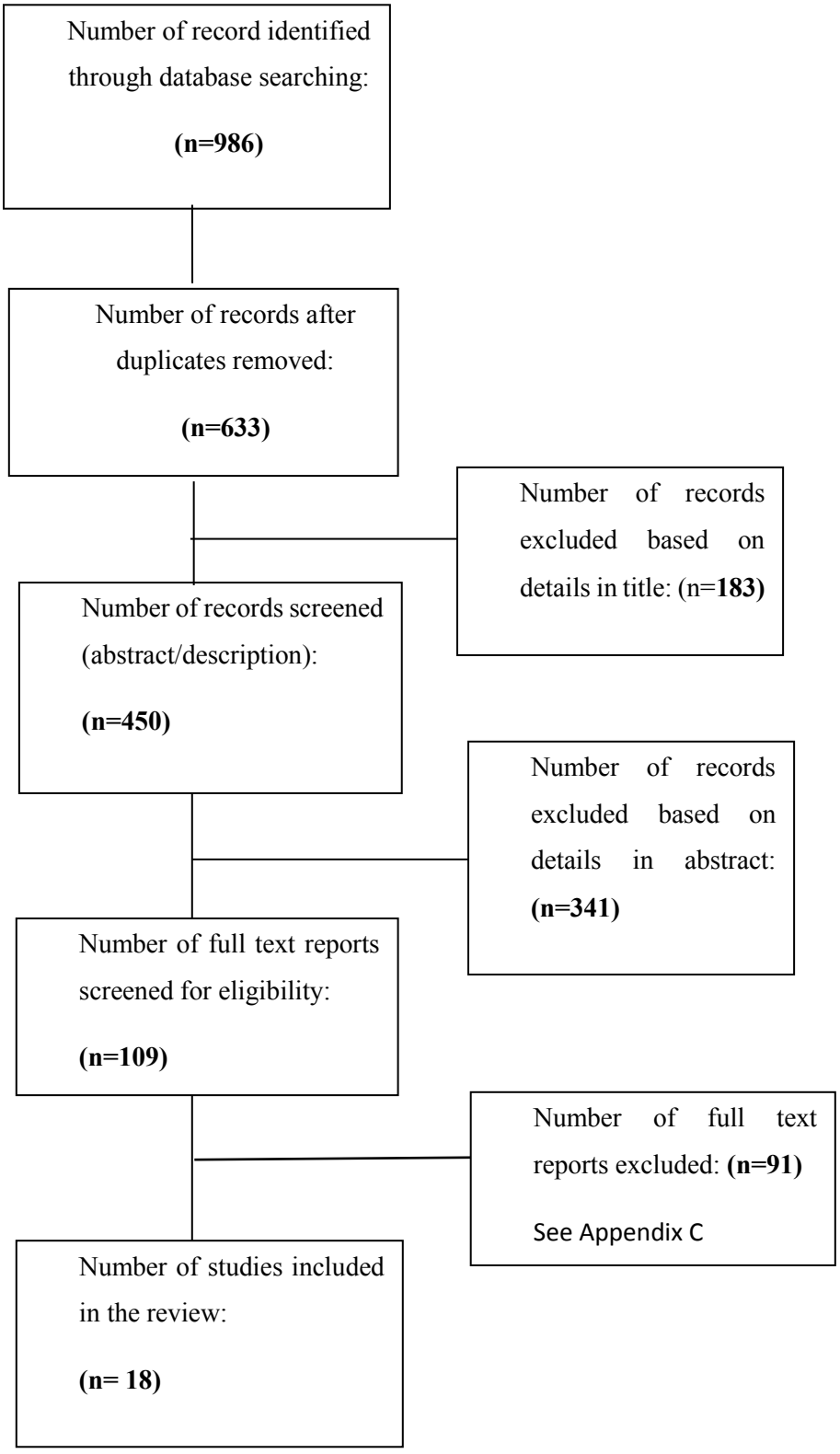


Table 1.2 Ratings of Study Quality for Included Studies

	Sampling	Design & Method	Analysis		
	Recruitment Method	**Fibromyalgia Measure**	**Power & Sample Size**	**Statistical Analysis**	**Confounding Variables**
Akkaya, 2012	no	yes	partial	yes	yes
Alanoglu, 2005	no	no	no	partial	yes
Andrell, 2014	partial	no	yes	partial	no
Avila, 2014	no	yes	no	partial	partial
Batmaz, 2013	no	no	no	partial	no
Birtane, 2007	no	yes	no	partial	yes
Cardoso, 2011	no	no	no	yes	no
Carillo, 2015	no	yes	partial	partial	no
Kolahi, 2010	no	no	yes	no	yes
Neumann, 2000	no	no	yes	no	no
Pagano, 2004	no	yes	no	partial	partial
Roshan, 2008	no	no	yes	partial	yes
Salaffi, 2009	partial	no	yes	yes	yes
Segura, 2015	partial	yes	yes	yes	yes
Smith, 2010	partial	no	no	partial	yes
Tander,, 2008	no	yes	no	partial	yes
Turkyilmaz, 2012	no	yes	no	partial	yes
Tuzun, 2004	no	no	no	partial	yes

Table 1.3 Summary of studies included in review.

Author, Year, Country	Sample Size	Recruitment	% female	Mean Age (SD)	Mean Disease Duration	Measure of FM	SF-36 PCS	SF-36 MCS
Akkaya et al., 2012 Turkey	FM= 51 CG= 41	Outpatient	FM=100 CG=100	Total Sample=35.5(9.9)	2.8(2.2)	FIQ FM= 70.8 (13.2) CG= 8.2 (9.6)		
Alanoglu et al., 2005 Turkey	FM= 34 CG= 22	Outpatient	FM=100 CG=100	Total Sample=37(10)	1.5(1)	TPC		
Andrell et al., 2014 Sweden	FM= 203 CG= 1055	Outpatient	FM=100 CG=52	Total Sample=46			FM=28.7(7.7) CG=50.0(9.4)	FM=38.0(13.7) CG=49.7(10.7)
Avila et al., 2014 Brazil	FM= 20 CG= 20	Outpatient	FM=95 CG=90	Total Sample=32.7(9.1)		FIQ FM=52(13.54) HC=26.0 (16.06)		
Batmaz et al., 2013 Turkey	FM= 37 CG= 35	Outpatient	FM=0 CG=0	Total Sample= 37.2(8.4)		VAS		
Birtane et al., 2007 Turkey	FM= 30 CG= 30	Outpatient	Not reported	Total Sample= 45.8(7.0)		FIQ		
Cardoso et al., 2011 Brazil	FM= 16 CG= 15	Outpatient	FM=100 CG=100	FM=53.5(7.5) CG=54.1(4.4)		SSB		
Carrillo et al., 2015 Spain	FM= 52 CG= 55	Outpatient	FM=100 CG=100	FM=46.2(9.4) CG=45.1(9.4)	6.5(5.0)	FIQ FM=62.9(16.2)		
Kolahi et al., 2010 Iran	FM= 100 CG= 100	Outpatient	FM=100 CG=100	FM=49.9(7.7) CG=46.6(6.5)		VAS	FM=60.5(9.4) CG=58.5(9.5)	FM=74.5(10.9) CG=69.8(11.9)
Neumann et al. 2000 Israel	FM= 90 CG= 50	Outpatient	FM=100 CG=100	FM=48(10) CG=55(13)	10(3)	VAS		
Pagano et al., 2004 Brazil	FM= 40 CG= 40	Outpatient	FM=100 CG=100	FM=49.5(6) CG=49.5(6)		FIQ		
Roshan et al., 2008 Iran	FM= 80 CG= 74	Outpatient	FM=100 CG=100	FM=42.9(9.1) CG=37.2(10.3)	10(3)			

Salaffi et al., 2009 Italy	FM= 380 CG= 1579	General Population	FM=92 CG=50	FM=52.1(10.8) CG=53.9(12.9)	10.5(9.7)	VAS	FM=38.6(6.9) CG=49.7(9.0)	FM=32.8(10.9) CG=45.6(8.4)
Segura-Jimenez, 2015 Spain	FM= 459 CG=214	FM Association	FM=100 CG=100	FM=52.2 (7.1) CG=51.3(7.0)		FIQ-R FM=64 (14.7) CG=22.4 (15.6)	FM=29.9(8.4)) CG=46.9(10.5)	FM=35.9(12.6) CG=47.7(18.9)
Smith et al., 2010 USA	FM= 41 CG= 44	General Population	FM=100 CG=100	Total Sample= 48.4 (6.9)			FM=32.4(19.6) CG=89.4(8.9)	FM=39.6(19.7) CG=85.0(9.5)
Tander et al., 2008 Turkey	FM= 30 CG= 30	Outpatient	FM=100 CG=100	FM=40.0(1.1) CG=40.4(1.0)	5.23(0.9)	FIQ=51.70(2.26)		
Turkilmaz et al., 2012 Turkey	FM= 37 CG= 31	Outpatient	FM=100 CG=100	FM=39.2(6.5) CG=39.1(6.2)		FIQ FM=64.8(15) CG= 21 (8.5)	FM=42.6(17.0) CG=57.6(17.3)	FM=49.3(18.5) CG=60.8(17.1)
Tuzun et al., 2004 Turkey	FM= 33 CG= 33	Outpatient	FM=100 CG=100	FM=41.6(7.3) CG=38.9(5.4)	8.6(6.6)	VAS		

Note. Sample Size: FM=Fibromyalgia; CG=Control Group; **Measure:** FIQ= Fibromyalgia Impact Questionnaire; FIQ-R= Fibromyalgia Impact Questionnaire-Revised; VAS= Visual Analogue Scale;

1.3.7 Meta-analysis of the eight subdomains of the SF-36

The pooled mean scores on the eight SF-36 subscales for individuals with FM (Table 1.4), with 95% confidence intervals (CI) indicates that the least affected subdomain on the SF-36 is Social Functioning. The worst affected subdomain for individuals with FM appears to be Physical Role. The subdomains related to physical health apart from Physical Functioning (Physical Role, Bodily Pain, and General Health) showed lower mean scores than the subdomains related to mental health apart from Vitality (Emotion Role, Social Functioning and Mental Health).

Table 1.4 FM Participants Meta-analysed Pooled Mean Scores of the SF-36 subdomains (each subscale score from 0-100; higher scores indicates better HRQoL)

SF-36 Subgroups	Mean	Confidence Intervals 95%	Heterogeneity I^2
Physical Functioning	49.89	45.38 , 54.40	96.58
Physical Role	28.37	21.37, 35.37	98.14
Body Pain	33.98	29.70, 38.27	97.65
General Health	39.33	34.67, 43.98	97.81
Vitality	37.09	32.58, 41.60	98.64
Social Function	52.88	48.06, 57.70	97.34
Emotion Role Function	42.68	36.63, 48.74	96.03
Mental Health	50.81	46.99, 54.62	96.14

Table 1.5 presents the pooled mean differences between individuals with FM and healthy controls. Forest plots of each domain meta-analysis can be found in Appendix E. On all eight subscales of the SF-36, there were significant differences found between the FM group and

healthy controls with the healthy controls reporting a significantly better level of HRQoL. Appendix F includes forest plots for the differences between individuals with FM and healthy controls with regards to the meta-analysed SF-36 subdomains. The greatest difference appeared to be in relation to the subdomains of Physical Role, Emotional Role, Bodily Pain and Physical Functioning.

Table 1.5 Meta-analysed differences between FM and HC groups on SF-36 subgroup scores

SF-36 Subgroups	Mean Difference	Confidence Intervals 95%	Heterogeneity I^2
Physical Function	-33.92	-40.31 , -29.53	95.87
Physical Role	-53.39	-62.92, -43.87	97.92
Body Pain	-38.23	-43.97, -32.48	96.94
General Health	-31.11	-35.91, -26.31	95.45
Vitality	-29.41	-34.59, -24.24	96.40
Social Function	-24.35	-30.53, -18.17	96.83
Emotion Role Function	-37.48	-45.92, -29.03	96.33
Mental Health	-21.24	-24.82, -17.65	91.57

1.3.8 Meta-analysis of the two subcomponents of the SF-36 (PCS and MCS)

The pooled overall scores for PCS and MCS for six studies that reported these components was 38.8 (95% CI: 31.2-46.4) and 42.3 (95% CI: 34.3-50.2). Figure 1.2. It was found that there were no significant differences between the PCS and MCS scores for individuals with FM (MD-3.31; 95% CI, -9.45, 2.84 with high heterogeneity among studies I^2= 97.72).

Figure 1.2 Meta-analysed difference between PCS and MCS for FM individuals

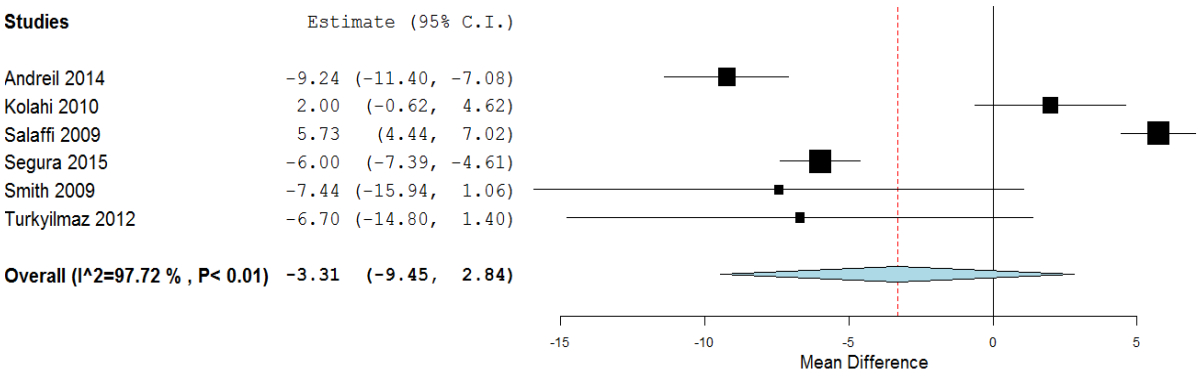
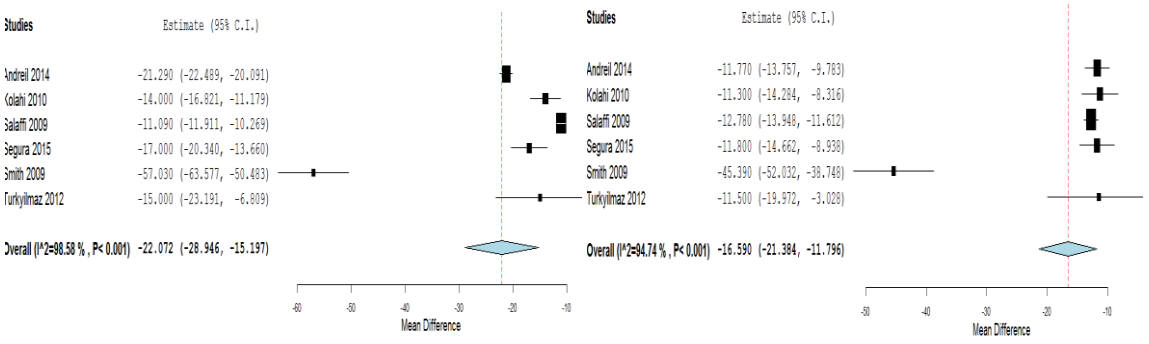


Figure 1.3 presents the forest plots representing the pooled mean differences for PCS and MCS between individuals with FM and healthy controls. Six studies compared scores on the PCS in individuals with FM and healthy controls. Individuals with FM had significantly lower scores on the PCS compared with healthy controls (MD-22.07; 95% CI, -28.95, -15.20 with high heterogeneity among studies I^2= 98.58). Six studies compared scores on the MCS in individuals with FM and controls. Individuals with FM had significantly lower scores on the MCS compared with healthy controls (MD-16.59; 95% CI, -21.38, -11.80 with high heterogeneity among studies I^2= 94.74). It can be seen that there were greater differences between the individuals with FM and healthy control on the PCS compared to the MCS.

Figure 1.3 Meta-analysed difference between PCS and MCS in individuals with FM compared to healthy controls



PCS **MCS**

1.3.9 Sensitivity and subgroup analysis

Appendix G presents the pooled mean differences between individuals with FM and healthy controls on the SF-36 sub-domain scores according to each sensitivity and subgroup analysis. Sensitivity analysis explored the exclusion of studies that did not receive a 'yes' or in some cases 'partial' on the methodology quality criteria in relation to sampling methods; measures of FM symptom severity, power/sample size; reporting effect sizes and p-values; and controlling for confounding variables. The subgroup analyses were conducted according to area of origin.

The sensitivity analysis found that the level of heterogeneity remained in the high range (I^2=>75) despite excluding studies based on the quality of the methodology. After excluding 14 studies for using convenience sampling, the four studies that were awarded 'partial' (Andrell, 2014; Salaffi et al., 2009; Segura-Jimenez et al., 2015; Smith et al., 2010) showed a reduction in heterogeneity on BP(I^2=11.1) and MH (I^2=0) sub-domains. The subgroup analysis indicated that area of origin did reduce heterogeneity: on PF (I^2=0), PR (I^2=0), GH (I^2=50.1), VT (I^2=0), ER (I^2=0) for Iran/Israel (Kolahi et al, 2010; Roshan et al., 2008); on PF (I^2=49.39), BP (I^2=43.25), and MH (I^2=49.34) for America/South America (Avila et al., 2014; Cardoso et al., 2011; Pagano et al., 2004; Smith et al., 2010); and on MH (I^2=0) for Europe/Scandinavia (Andrell et al., 2014; Carrillo et al., 2015; Salaffi et al., 2009; Segura-Jimenez et al., 2015). Heterogeneity remained in the high range for all Turkish (other) studies (Akkaya et al., 2012; Alanoglu et al., 2005; Batmaz et al., 2013; Birtane et al., 2007; Neumann et al, 2000; Tander et al., 2008; Turkyilmaz et al., 2012; Tuzun et al., 2004). Sensitivity and subgroup analysis were not conducted to explore heterogeneity for the PCS and MCS scores as there were only six studies (Egger, Smith, Schneider, & Minder, 1997).

1.3.10 Narrative synthesis of key findings

In total, 11 out of 18 studies included in the review reported a significant difference in all subdomains of the SF-36 between individuals with and healthy controls (Alanoglu et al., 2005; Andrell et al. 2014; Avila et al. 2014, Batmaz et al., 2013; Birtane et al., 2007; Carillo et al 2014; Pagano et al. 2004; Salaffi et al. 2009; Smith et al., 2010; Segura-Jimenez et al., 2015; Tuzun et al. 2004).

This meta-analysis calculated that Physical Role compared to the other eight SF-36 subdomains showed the greatest difference between individuals with FM and healthy controls. The forest plots (Appendix F) demonstrated that Pagano et al. (2004) compared to the other studies in the review reported the greatest difference between the FM group and the HC group in relation to PR. Pagano et al. (2004) matched controls for age and BMI, which received a 'partial' quality criteria rating for addressing confounding variables. The FIQ was also used but Pagano et al. (2004) did not report the total score of the FIQ or the mean differences between the FM and HC group to show the difference in severity of symptoms between the two groups. Turkyilmaz et al. (2012) on the other hand did not find any significant difference between the individuals with FM and healthy controls on the PR subdomain, however this study controlled for a number of variables which are known to impact quality of life e.g. BMI, marriage, education, occupation, economic status, mood. In term of addressing confounding variables on the methodology quality criteria, this study was awarded 'yes'. The FIQ was also used in this study and it was found that while there was a significant difference between individuals with FM and healthy controls, the total figures reported for the healthy controls were slightly higher than what has been previously reported in other studies (Akkaya et al., 2012; Sivas, Baskan, Aktekin, 2009). This may indicate that there was a slightly higher level of symptom severity in the control sample which may explain the lack of significant difference between individuals with FM and healthy controls in relation to this subdomain. This is in line with the finding that there is a strong correlation between the FIQ and the PR subdomain ($r=0.481$; $p< 0.007$; Birtane et al., 2007). Cardoso et al., (2011) also did not report a significant difference on PR along with four other subdomains (VT, SF, ER, and MH). It must be noted that Cardoso et al., 2011 reported the smallest sample size (N=16) of all the studies in this review and received a 'no' rating on the methodology quality criteria for power. It is likely that the lack of significant differences between individuals with FM and healthy controls were a result of the study being insufficiently powered.

While this meta-analysis found PR to be the subdomain which was most negatively affected in the FM group compared to the HC group, the SF subdomain was reported to be the least negatively impacted between these two groups. Four of the 18 studies (Akkaya et al. 2012; Cardoso et al., 2011; Roshan et al., 2008; Turkyilmaz et al., 2012) reported that SF was not statistically significant between individuals with FM and healthy controls. Of particular

interest was Roshan et al., (2008) study whereby SF score was found to be higher in individuals with FM than the healthy controls. Roshan et al. (2008) controlled for marital status, education, occupation as well as age which may have resulted in them finding a similar SF and MH score in both individuals with FM and healthy controls. Two other studies in this review also found that MH was not statistically significant (Tander et al., 2008; Cardoso et al., 2011). Tander et al., (2008) assessed for depression by using the Beck Depression Inventory (BDI) whereby a score of >17 was considered to be a sign of depression. It may be that individuals with FM and healthy controls did not differ significantly on MH because the BDI eliminated the possibility of individuals with co-morbid depression.

Ten studies (Alanoglu et al., 2005; Andrell et al., 2014; Avilia et al., 2014, Birtane et al., 2007, Cardoso et al., 2011, Kolahi et al., 2010, Pagano et al., 2004, Roshan et al., 2008, Salaffi et al., 2009, Smith et al., 2010) in this review did not use any standardised depression measure to account for co-morbid depression which may increase the likelihood of a significant difference being present between individuals with FM and healthy controls on the MH subdomain as previous studies have indicated the high prevalence of co-morbid depression in individuals with FM (Fuller-Thomson, Nimignon-Young, Brennenstuhl, 2012). Two studies reported that when comparing individuals with FM and healthy controls they did not find a significant difference in all of the SF-36 domains, however these studies did not include p-values to specify which subdomains were insignificant (Kolahi et al., 2010; Neumann et al. 2000). For this reason, these two studies were awarded 'no' on the methodology quality criteria for statistical analysis as the lack of p-values limited the possibility of interpretation and comparability of results.

In terms of the PCS and MCS component scores it was found there were no significant difference between these components in individuals with FM. All five studies showed a slightly higher mean score for PCS compared to MCS except for Salaffi et al. (2009). It may be worth noting that apart from Segura et al. (2015), Salaffi seemed to receive the best ratings across all the methodology quality criteria. In their study they found that the PCS was influenced by widespread pain, education level and BMI whereas MCS was correlated with widespread pain, sleep abnormalities, physical functioning, fatigue, gender and low educational level. As Salaffi et al. (2009) used a general population, this sample may be more representative of individuals with FM as it reduces bias from help seeking (Mas et al., 2008).

Overall, the six studies seemed to confirm that the PCS is more severely affected in individuals with FM compared to healthy controls.

1.4 Discussion

Studies conducted across different geographical areas showed that individuals with FM had a consistent pattern of HRQoL impairment. Overall individuals with FM scored significantly lower on all eight health status domains compared with individuals in the general population. The results of this review show that individuals with FM have lower levels of HRQoL, in particular Physical Role. This is in line with previous literature which suggests that individuals with FM have poor scores on the physical dimensions of HRQoL (Campos et al., 2012). Social Functioning and Mental Health were the least affected subdomains in this review for individuals with FM. A study carried out by Alonso et al. (2004) that used the SF-36 across eight different countries found Social Functioning and Mental Health to be the least affected in relation to chronic illnesses. These results were consistent with a similar review carried out among individuals with rheumatoid arthritis (Matcham et al., 2014). The relatively low impact of these diseases on social functioning and mental health may be explained by individuals being able to adapt to the conditions of the disease and/or adopting new lifestyle behaviours. It may also be related to cultural aspects as it was found that social functioning was least affected in an Iranian study (Roshan et al., 2008). This is in line with other systematic reviews that have found social functioning to be the least affected subdomain in an Iranian population with rheumatoid arthritis (Shokri, Mottaghi, Qolipour, 2015) and an elderly population where it was suggested that individuals may be able to access social support from family and society due to the values and emphasis on community (Tajvar, Arab, Montazeri, 2008). One reason that Roshan may have found higher rates of SF than the control group was that the study controlled for marriage, education and occupation which have been found to be predictors of better related quality of life for Iranians with rheumatoid arthritis (Shokri et al, 2015).

The greatest difference between individuals with FM and healthy controls were in the domains of Physical Role, Emotional Role, Bodily Pain and Physical Functioning. Other studies have suggested that the functional loss through incapacity to work and drop in income because of pain and fatigue may impact on a person's perceived health related quality of life (White, Speechley, Harth, & Ostbye, 1999).

The quality of studies appeared to be good, however the majority of studies used sampling criteria that limited their external validity due to a small number of studies investigating population based samples (Salaffi et al. 2009; Smith et al., 2010). Studies that used convenience sampling recruited participants from hospital outpatient clinics, which may represent the most affected individuals with FM. Therefore, these results may not be an accurate representation of the FM population (Mas et al., 2008). On the other hand, smaller sample sizes (Avila et al., 2014; Cardoso et al., 2011) may represent only patients who present themselves for research participation, who in turn, would usually represent a healthier patient group (Knudsen, Hotopf, Skogen, Overland, & Mykletun, 2010).

This review focused on one specific factor, HRQoL, however the majority of studies in this review explored a broad range of factors relating to FM such as auditory event related brain potentials (ERBP; Alangolu et al., 2005). While ERBP was relevant to FM, it was not related to HRQoL in FM. Therefore, this approach may not be the most appropriate as it may result in participant fatigue, with participants completing large batteries of questionnaires (Johnson et al, 2011). Moreover, it possibly will result in Type 1 error by increasing the likelihood of false positives. A small number of studies (Neumann et al., 2000) controlled for this by using adjustments to the criteria for significance such as the Bonferroni correction. However, this could increase the likelihood of Type II error (Perneger, 1998), a preferable alternative would be to conduct studies that included a smaller number of factors which may be more relevant to HRQoL.

Increased BMI, lower education levels, marriage status, lower employment have been associated with poorer SF-36 scores (Cherapanov, Palta, Fryback et al., 2011). These factors were controlled for in a number of studies, however only one study controlled for them using a multiple regression. For this reason, it was not possible to look at whether these factors predicted poor HRQoL in individuals with FM. Although individuals with FM and the control group were matched for age, some studies applied an age-criteria in order to match the groups (Cardoso et al., 2011; Pagano et al., 2004; Roshan et al., 2008; Segura-Jimenez et al., 2015), which may have introduced bias to the review. Overall studies tended not to include

participants over the age of 65, limiting the generalisability of the impact of FM on quality of life in older adults. This further reduces the interpretation and comparability of studies.

All studies used the ACR 1990 criteria for identifying FM rather the 2010 preliminary criteria. While there is good agreement between the 1990 and 2010 criteria, it has been argued that the 2010 criteria have lower specificity and higher sensitivity (Goldenberg, 2009). This finding suggests that there is a higher possibility that individuals with other functional diseases but not generalised pain may be identified as having FM when using the 2010 ACR criteria (Carrillo et al., 2015). All of the studies in this review included predominantly female populations, which is in line with the literature reporting that 90% of individuals with FM are women (Yunus, 2002).

The high level of heterogeneity identified in the meta-analysis may be explained by variation in the study population including disease duration and symptom severity. While a number of studies accounted for variables such as gender, ethnicity, and marital status, a number of studies did not assess severity of symptoms. Eight studies in the review used a standardised measure for symptom severity and only six of these reported the values. Individuals with Fibromyalgia are a heterogeneous group and the rating number and impact of different symptoms are expected to vary between different populations (Branco et al, 2010). Research in this area has proposed a model of clustering individuals with FM into two categories based on physical symptoms and psychological symptoms of the FIQ (de Souza, Goffaux, Julien et al., 2009; Calandre, Garcia- Carrillo, Garcia-Leiva, 2011). Therefore, it would be useful to carry out a meta-analysis in the future looking at the impact of symptoms using the FIQ on the eight subdomains of the SF-36 to see if this may help to reduce the level of heterogeneity in the research.

Sensitivity analyses did not reveal that the results were sensitive to the study methodology except in relation to sampling. Random sampling or recruiting from a number of areas rather than convenience sampling seemed to reduce heterogeneity in BP and MH. It is surprising that heterogeneity was reduced in BP as pain tends to be variable among individuals with FM (Schaeffer, 1997) with average daily pain ratings varying in individuals depending on time of day (Okifuji, Bradshaw, Donaldson, 2011). Subgroup analysis in relation to geographical origin succeeded in reducing some of the heterogeneity. Reasons for this may be in relation to culture or the different translations of the SF-36; mean scores may not be comparable due to

different cultural variation in both phrasing of items and responses and in interpretation of the concept of HRQoL (Bullinger, Alonso, Apolone et al., 1998).

1.41 Strengths, limitation and implications for future research

Limitations of this review were that all studies were cross-sectional and therefore causation of poor HRQoL in individuals with FM could not be inferred. However, this review indicates that the physical role is most negatively affected in individuals with FM and provides a rationale upon which more methodologically rigorous experimental studies can be developed. In particular, it would be useful to look at what factors may be predictive of poor scores on physical role e.g. physical activity (Kop, Lyden, Berlin, Ambrose, Olsen, 2005) in individuals with FM which could help to develop intervention studies.

This study only considered studies that used the SF-36 to measure HRQoL, which may have excluded studies that were potentially relevant. For example, Mas (2008) recruited from the general population and compared HRQoL using the SF-12 in individuals with FM and healthy controls. This data would have been useful as the external validity of the study was strong, however, it would not have been possible to include in the meta-analysis.

A strength of the current review was that authors were contacted for further information such as PCS and MCS scores. Therefore, by providing the two higher summary scores along with subdomain scores, this review was able to show that the impact is significant in both physical and mental domains. The findings from this review show that while scores on the physical domains were poorer than the mental domains, treatment of FM should incorporate interventions that target helping people to improve both physical and mental components. This suggestion is in line with the SIGN Guidelines (2013) for chronic pain stipulating that a multidisciplinary team should be involved with chronic pain conditions. They also suggest that people with pain conditions tend to focus more on physical symptoms, therefore when referring patients for psychological assessment it should be clarified that the aim of a psychological intervention is to increase coping skills and improve quality of life.

Finally, many of the studies did not include information about severity of FM symptoms or mood ratings such as depression or anxiety, it was not possible to specify the association between the HRQol and potential clinical factors contributing to low HRQoL. All of the above

limitations suggested, indicates that further research is needed to confirm the findings of this study.

In conclusion the review demonstrated that individuals with FM have a lower level of HRQoL particularly on the Physical Role domain. Considering the level of heterogeneity of the evidence, this conclusion should be interpreted with caution. As it was not possible to obtain individual patient data for this review, aggregate data was used, however individual patient data would be recommended for future research in this area as it can improve the quality of the data and the type of analyses that can be performed (Stewart & Tierney, 2002).

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Journal Article 2

The relationship between a two factor model of self-compassion, self-esteem and pain in a chronic pain population

Authors

Caitríona Doughty, Dr. Laura Keith, Dr. Paul G. Morris, & Dr. Nuno Ferreira

Affiliations

Department of Clinical Psychology NHS Fife, Clinical and Health Psychology, University of Edinburgh Scotland.

Corresponding Author

Caitríona Doughty, Clinical Psychology Department, Lynebank Hospital, Halbeath Road, Dunfermline, Fife, KY11 4UW

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Abstract

Objectives: This study aims to explore the predictive role of self-compassion (self-warmth and self-coldness) and self-esteem in key outcomes of quality of life and disability in a chronic pain population.

Methods: A quantitative cross-sectional design was used. Sixty participants, recruited through NHS chronic pain services and pain self-management groups, completed measures of pain severity, self-compassion, self-esteem, distress, quality of life and disability. Correlation and hierarchical regression were used to explore relationships between these variables.

Results: Quality of life was lower than previous research, with females reporting higher levels of quality of life than males. After controlling for demographic and clinical variables, self-warmth was a significant predictor quality of life, however it was not predictive of disability. Neither self-coldness nor self-esteem were significant predictors of quality of life or disability.

Discussion: Self–warmth is associated with better quality of life in people with chronic pain. Psychological interventions targeting the development of self-warmth attributes and skills may have beneficial effect in the psychological adjustment of people suffering with chronic pain. Further research is needed to replicate these findings with a larger and more representative sample.

Keywords: self-compassion, self-esteem, self-coldness, self-warmth, quality of life, chronic pain,

2.1 Introduction

Chronic pain has been defined by the Scottish Intercollegiate Guidelines Network as the experience of pain for at least three months that does not resolve with treatment [1]. With a worldwide estimated prevalence of 19-34%, [2,3] chronic pain is estimated to be one of the conditions with greatest socio-economic costs.[4] As the burden of chronic pain increases, predictors and outcomes of chronic pain have received growing attention [5]. Psychological factors are widely accepted as influencing the relationship between chronic pain and outcomes such as disability and distress.[6] Psychological approaches have been applied in chronic pain management and seem beneficial.[7] However, psychological treatments for chronic pain have shown small effect sizes and further development is required [8]. It has been suggested that a focus on understanding the treatment mechanisms or processes may help to increase the efficacy of these treatments.[9] One set of processes that have started to receive growing attention in the area of chronic pain are those related to self or personal identity such as self-compassion and self-esteem.[10]

2.1.1 Evidence for Self-Compassion as a Predictor

It has been suggested that positive affect may provide a buffering function to health problems associated with negative emotions in patients with chronic illness [11]. The role of self-compassion was explored in a chronic illness group and a cancer group in relation to psychopathology and quality of life [12]. Pinto-Gouveia et al. (2013) used a two-factor model of the Self-Compassion Scale referred to as self-coldness and self-warmth and it was found that self-coldness was the best predictor followed by self-warmth for quality of life in the chronic illness group. However Pinto-Gouveia et al. (2013) also found that self-warmth was the best predictor of quality of life for individuals with cancer. Pinto-Gouveia et al.

(2013) study reported limited demographic and clinical information and controlled only for education level, therefore it was difficult to infer what factors may have influenced the differences between the groups e.g. gender, age, severity of pain. Several studies have revealed that pain severity and distress are factors that contribute to poor quality of life and disability.[13,14] Participants in Pinto-Gouveia et al. (2013) study were predominantly female and middle aged. A recent meta-analysis by Yarnell et al., (2015) suggested that while gender differences on levels of self-compassion were significant, only a small effect size was observed.[15] Neff and Pommier (2013) proposed that women are often assigned the role of caregiver in society, however they are less able than men to relate to themselves with the same level of compassion that they would show to others.[16] It was also found that females tend to be more critical of themselves and demonstrate more negative self-talk than males. Age has been found to reduce the effect of gender differences on levels of self-compassion.[15] Ardelt et al (2010) argued that the understanding of common humanity is a wisdom that is more likely to increase with age regardless of gender because people have more life experience to reflect upon.[17]

2.1.2 How Self-Compassion is conceptualised and measured

Self-compassion has been defined as comprising three main components: 1) self-kindness in the absence of self-judgement or self-criticism; 2) common humanity whereby an individual perceives their struggle as part of a shared human experience rather than an isolated experience; 3) mindfulness without over-identification in relation to negative thoughts or feelings. It is argued that when these components interact, an individual has the tendency to be caring, warm and understanding towards oneself regardless of one's successes or failures [18].

Self-compassion has been suggested to improve awareness and emotion regulation associated with psychopathology [19-21]. MacBeth et al. (2012) conducted a meta-analysis on the relevance of self-compassion for the emotional symptoms of anxiety, depression and stress.[21] Findings showed that self-compassion is related to psychopathology, identifying a large effect size. Associations were reported to be significant regardless of clinical status, age or gender. This meta-analysis used the total score from Self-Compassion Scale (SCS) [22] and the Self-Compassion Scale-Short Form (SCS-SF) [23] rather than specific subscale scores. A recent meta-analysis by Muris et al (In Press) focused on the subscales of the SCS and SCS-SF in relation to psychopathology.[24] It was found that the associations between the negative subscales of the SCS (self-judgement, over-identification, isolation) and psychopathology were significantly stronger than the positive subscales of the SCS (self-kindness, common humanity and mindfulness). This suggests that the use of a total compassion score of the SCS or SCS-SF, which includes the reversely scored negative subscales, will potentially result in an inflated association with symptoms of psychopathology. This would result in an overestimation of the presumed protective role of self-compassion in mental health problems. Including both positively and negatively worded items in questionnaires were introduced with the aim of reducing response bias, however studies have shown that it can potentially undermine the quality of the assessment.[25] This may be the case for the SCS as a recent factor analysis did not support its construct validity when using a total score. [26, 27] For this reason, some researchers into self-compassion have started separating the positive (self-kindness, common humanity, mindfulness) and negative (self-judgement, isolation, over-identificaion) aspects of self-compassion into two dimensions known as self-warmth and self-coldness (Gilbert, McEwan, Matos, & Rivis, 2011).[28]

It has been suggested that to clarify the protective nature of self-compassion, it would be appropriate to discard self-coldness (self-judgement, isolation and over-identification) from the questionnaire and to focus solely on self-warmth (self-kindness, common humanity and mindfulness).[15] In addition, compassion focused interventions have reported specific improvements in positive affect, but they do not seem to effectively reduce negative affect more than any other intervention [28, 29]. This conclusion may be explained as a lack of large-scale, high-quality trials rather than the existence of negative evidence.[30]

Although there is evidence to suggest that self-compassion is associated with increased motivation in relation to positive health behaviours,[31] this element is not represented in the items of the SCS or SCS-SF. As a result, the three aspects of self-warmth (self-kindness, common humanity and mindfulness) are not necessarily distinctive of compassion but seem to tap a number of already known protective factors. For example, there is a vast amount of research evidencing that mindfulness on its own promotes well-being in chronic pain populations. [32]

Constructs such as belongingness [33] and self-soothing [34] closely resemble Neff's [18] dimensions of common humanity and self-kindness. It would be useful to explore which components of self-compassion are important within the context of psychopathology. [24] This is also true for the relative importance of self-compassion as compared with other constructs that have been advocated in the positive psychology literature such as self-esteem.[24] Although global self-esteem is considered to be less stable and more reactive than self-compassion,[35] both concepts are viewed as highly relevant for a person's general feeling of self-worth and as such it is not surprising that their link has often been studied

in previous research.[81,35-37] Thus, in order to study the unique relationship between self-compassion and mental health problems, it seems important to control for global self-esteem.

2.1.3 Overlap with other concepts

High self-esteem has been found to be a resource for coping with illness,[38] buffering against depression, stress, and negative emotions.[39,40] In particular, self-esteem has been linked to psychological adjustment in various chronic diseases such as cystic fibrosis, multiple sclerosis and HIV.[41-43] Conversely, illness may impact negatively on self-esteem.[44] Self-esteem may be threatened by experiencing illness-related consequences, or by decreased coping with everyday life challenges.[45,46] In turn, low self-esteem may lead to unhealthy behaviours in an attempt to self-regulate negative emotions.[47] A previous longitudinal study suggests that low self-esteem causes more negative affect for chronic disease patients than healthy populations.[39] As self-esteem can be an important coping resource, one of the concerns raised by the combination of low self-esteem and chronic illness is an increased difficulty in preventing the negative affect from developing into a more severe case of depression. Research demonstrated that patients with chronic pain who had lower self-esteem reported more negative affect, less positive affect and greater symptom severity than individuals with higher self-esteem.[38]

Neff [48] distinguished self-compassion from the related construct of self-esteem by proposing that self-esteem is based on evaluating oneself in comparison with others whereas self-compassion is based on relating to oneself without self-evaluation or comparison. Despite the benefits of self-esteem, studies show that what people do to get and maintain a sense of high self-esteem is linked to negative outcomes such as narcissism

and increased aggression.[49,50] Reasons for this may be that self-esteem is often dependent on favourable comparison with others and successful attainment which results in fluctuation depending on one's successes or failures.[48]

A number of studies have been conducted to investigate the cognitive and emotional processes by which self-compassionate individuals manage negative life events.[51] It was evidenced that self-compassion accounted for unique variance in the outcome variables when controlling for self-esteem. It was also reported that because self-compassion is not evaluation based, self-compassion appears to be a more stable and unconditional form of self-regard than self-esteem.[35] It must be noted that the situations the participants were dealing with in these studies [51] were unchallenging such as receiving a poor grade on a test or neutral feedback in comparison to many of the hardships people encounter in daily life. Therefore, their research shows that being self-compassionate helps people deal with real and imagined negative events, but the question remains of the degree to which treating oneself kindly buffers people against the impact of severe challenges in everyday life such as chronic pain.

In a study examining resilience levels in adults with congenital spinal bifida, it was found that chronic pain negatively impacted on self-esteem and self-compassion. This is in line with previous research in that disability severity can result in frustration and distress.[52] The findings that self-esteem and self-compassion correlate with resilience are consistent with the idea that having a source of positive self-regard and an ability to be kind to oneself is likely to promote positive adaptation when faced with adversity. A strong correlation was found between self-esteem and self-compassion (r=.688) which is in line

with previous findings [18,51,53,] raising the question of whether these are psychological distinct constructs.

2.1.4 Summary

Research in chronic pain has tended to focus on specific diagnoses, such as neuropathic pain [54] and fibromyalgia,[55] or on specific subgroups such as older people [56] and trauma survivors.[57] This focus on specific diagnoses/subgroups is limiting because many people with chronic pain do not have a clear diagnosis or precipitant for their pain.[58] For this reason, the present study did not focus on one particular pain condition.

Given the growing interest in the association between emotion regulation problems and unhelpful forms of self-relating with chronic pain, understanding the role of self-compassion and self-esteem may be potentially important variables in chronic pain in order to develop more effective treatment interventions. Muris et al. (In press) conducted a meta-analysis which found a significant link between self-warmth, self-coldness and mental health indicators.[24] Self-compassion also predicts unique variance in mental health after controlling for self-esteem. It was suggested that it would be useful to explore whether a two factor model of the SCS (self-warmth and self-coldness) is a better fit as this model seems to have stronger psychometric validity in both clinical and non-clinical samples.[59] A recent review of the literature indicated that the vast majority of studies (83.5%) relied only on the SCS or SCS-SF total score as an index of self-compassion.[24] Studies including self-esteem, self-warmth, self-coldness as predictors are limited in a clinical population and non-existent in a sample of participants with chronic pain. Previous literature has indicated that demographic variables such as age, gender and pain duration contribute to levels of self-compassion and pain outcomes including quality of life and

disability.[15,60] For this reason, the current study will control for relevant demographic variables when investigating self-warmth, self-coldness and self-esteem as predictors of disability and quality of life.

2.1.5 Aims

The main aim of the study was to determine whether and to what extent self-warmth, self-coldness and self-esteem would be unique predictors for pain outcomes while controlling for relevant demographic and clinical variables. We predicted that self-warmth and self-esteem would be (positively) associated with quality of life and (negatively) associated with disability, severity of pain and distress. We predicted that self-coldness will be (negatively) associated with quality of life and (positively) associated with disability, severity of pain and distress. It was hypothesised that self-warmth and self-coldness would be stronger predictors than self-esteem for pain outcomes, disability, and quality of life after controlling for known predictors such as demographic (e.g. gender and age) and clinical variables (e.g. distress and severity of pain)

2.2 Method

2.2.1 Design

This study used a cross-sectional, questionnaire-based design to explore relationships between self-warmth, self-coldness, self-esteem, and pain outcomes (distress, disability and quality of life). Ethical approval was granted by the NHS South East Scotland Research Ethics Committee (See appendix K).

2.2.2 Participants

During the period of February 2015 to February 2016, four hundred participants were invited to participate from the NHS Chronic Pain Service in Fife and Lothian, the NHS Fife Rheumatoid Disease Unit and the Fife Pain Association Scotland Self-Management Groups. Sixty individuals returned completed questionnaires (return rate= 15%). Forty percent of the responses were returned from the Chronic Pain Service in Fife and Lothian, eighteen percent from the NHS Fife Rheumatoid Disease Unit and forty-two percent from the Fife Pain Association Scotland Management Groups. Non-identifiable demographic information was collected in order to establish the characteristics of the sample. A total of 39 individuals (65%) were female and 21 individuals (35%) were male. Their mean age was 53.08 years (SD = 14.49) and their mean duration of pain was 11.2 years (SD= 10.7). Mean self-reported pain intensity and pain inference measured by the Brief Pain Inventory- Short Form (BPI-SF),[61] was 6.46 out of 10 (SD= 1.59) and 6.92 out of 10 (SD= 2). These pain scores for the BPI-SF subscales were similar to reported scores on the BPI-SF in other studies carried out in a chronic pain.[62] Participants had a variety of pain sites, with joint pain being the most common (34%), followed by back pain (28%), all over body pain (17%), and right sided pain (7%). The remaining pain locations were neck and leg. They reported having had a variety of treatments, with prescribed medication, physiotherapy and reflexology being the most commonly reported treatments.

2.2.3 Measures

Permissions for the use of copyrighted questionnaires were received prior to administration (Appendix I)

Demographics Questionnaire: Participants were asked to provide non-identifiable demographic data including age, gender, pain duration, diagnosis, and who provided their diagnosis.

Self-Compassion Scale: (SCS)[22] contains 26-items assessing how people typically act towards themselves in adverse circumstances. There are three factors of positive self-compassion: self-kindness; common humanity; and mindfulness, and three factors that focus on lack of self-compassion: self-judgement; isolation; and over-identification. This study obtained two separate scores for this scale: self-warmth (sum of three positive factors) and self-coldness (sum of the three negative factors). Responses to each item are measured on a five-point scale from "Almost never" to "Almost always". The scale has good predictive, convergent and discriminant validity and has been shown to have good internal consistency when used with a pain population (0.91-0.95).[60,63] Cronbach's alpha for the Self-warmth subscale in this sample was .92. Cronbach's alpha for the Self-coldness subscale in this sample was .91.

The Rosenberg Self-Esteem Scale: (RSES)[64] includes 10 statements related to feelings of self-worth or self-acceptance, and measures of global self-esteem. The response set for this scale was 1 (strongly agree) to 4 (strongly disagree) with total scale scores ranging from 10 (low self-esteem) to 40 (high self-esteem). The scale has good predictive, convergent and discriminant validity and [65] and has been shown to have good internal consistency when used in a clinical population for individual with HIV and Cystic Fibrosis with a Cronbach's alpha ranging from 0.85 to 0.94. [43,66] Cronbach's alpha for the RSES in this sample was .88.

Brief Pain Inventory- Short Form: (BPI-SF)[61] comprised 15 items and assesses for the presence of pain, pain severity and functional interference from pain (general activity, mood, walking, relationships with others, sleep, normal work and enjoyment of life) in the last 24 hours. For these subscales a higher mean score indicates higher pain severity and pain interference. It also assesses the types of pain medications being used, the percentage of pain relief obtained from medications and considers the distribution of pain via a body map. The BPI-SF has been used extensively in clinical trials for pain and has been recommended as a reliable and valid measure.[67] Internal consistency for the pain severity score and for the interference scale has been reported as ranging from 0.85 and 0.88 respectively.[68] Construct validity of the BPI-SF has been supported for the generic assessment of pain as well as specifically for low back pain and rheumatoid arthritis.[69] Cronbach's alpha for the BPI-SF in this sample was .91.

The Hospital Anxiety and Depression Scale: (HADS)[70] is widely used for measuring anxiety and depression in clinical population with physical illness. It contains 14 items and requires the respondent to rate the degree to which they have experienced emotions relating to distress in the past week. This scale provides an overall measure of emotional distress as well as depression and anxiety subscale scores. All items are rated on a four-point response scale (0-3). Cut off scores for both anxiety and depression are normal (0-7), mild (8-10), moderate (11-15) and severe (16-21).[70] A person with a total score of 15 or more (15+) on the HADS is considered to experience clinically significant emotional distress. [71] Across a wide range of samples the reliability and validity of the HADS has been well established with a Cronbach's alpha for each scale ranging between .67 and .93 [72,73] Cronbach's alpha for the HADS in this sample was .91.

Pain Disability Questionnaire: (PDQ)[74] incorporates a disability-related psychosocial component in addition to a physical functioning component related to pain. The psychosocial component consists of nine items and has a score range of 0-90, which measures how much pain effects mood, physical role, leisure activities. The functional status component contains six items and scores range from 0-60 and measures how much pain impacts on employment status, self-care, mobility and income. The PDQ yields a total functioning disability score ranging from 0 (optimal function) to 150 (total disability), using 10 point Likert scale.[75] The PDQ has good reliability with a Cronbach's alpha of .96. The construct related validity of the PDQ was found to be excellent as it correlated well to both the Million Visual Analog Scale (0.65-0.81) and Owestry Pain Disability Questionnaire (0.55-0.80).[74] Cronbach's alpha for the PDQ in this sample was .92.

Quality of Life Scale: (QOLS)[76] is a 16 item questionnaire that measures physical and mental well-being, relationships with other people, social, community and civic activities, personal development and fulfilment, recreation and independence. Each item was scored 1-7 and the total score ranges from 16-112. A higher total score shows a higher QOL. This scale has shown good validity and test-retest reliability.[7] Good internal consistency (α=0.88-0.93) was found in a number of studies with fibromyalgia participants and a coronary obstructive pulmonary disease population. [78,79] Cronbach's alpha for the QOLS in this sample was.93.

2.2.4 Procedure

NHS professionals in the Pain Management and Rheumatoid services, and facilitators in the Pain Association Self-Management Groups provided people attending these services with packs containing information about the study (Appendix L) and the six research

questionnaires (Appendix N) along with a general questionnaire collecting non-identifiable demographic information (Appendix M). Individuals who were interested in taking part in the study were given the packs to take home which they could then post back to the researcher using an included pre-paid envelope. Consent to participate was provided by the return of the (anonymous) research questionnaires. The questionnaires were marked with a unique identifier code for each recruitment site.

2.2.5 Statistical Analysis

All statistical analyses were conducted using IBM SPSS Statistics Version 22. The computational and modelling tool PROCESS [80] for SPSS was used for mediation analyses.

2.2.6 Power and Sample Size

Power analyses were conducted to guide recruitment. As the relationships between self-compassion, self-esteem and pain outcomes (disability and quality of life) had not previously been investigated in this population, a medium effect size was assumed (conservatively), based on previous studies between self-compassion and general psychopathology in adults (r = -0.54; 95% CI [-0.57, 0.51])[21] and chronic pain population (r's ranging from - 0.50 to -0.52) [73,60]. It was determined that in order to have .8 power to detect a medium effect size at an alpha level of .05 with six independent variables (gender, severity of pain, distress, self-warmth, self-coldness and self-esteem) and two dependent variables (disability, quality of life) a sample of 103 was required (G*Power Version 3.0.10).

2.2.7 Missing Data

Data was checked for missing items. Little's Missing Completely at Random (MCAR) Test was found to be non-significant ($\chi^2(72)= 65.74 p<.69$). As data was found to be MCAR, missing data was dealt with by using individual mean substitution.[82] This meant that for measures where up to one item per subscale was missing but less than 10% of total scale, and where there was homogeneity within subscales, individual mean substitution was adopted i.e. the inputted value was calculated from the mean of the available items of that subscale/total scale for the given respondent. While internal consistency can be positively skewed by using this method, it does allow for data to be included where limited items are missing. A total of 10 cases had missing items replaced using this method.

2.2.8 Tests of Reliability

Cronbach's alpha tests of internal consistency were calculated for key variables and subscales. Values above .7 are generally considered to suggest adequate levels of reliability.[83] Within this study reliability for all subscales and scales ranged from 0.76 to 0.93.

2.2.9 Data Analysis

Data was initially screened to ensure that assumptions of further analyses were met. Histograms and boxplots were examined to ensure no outliers were present. Assumptions of linearity and homoscedasticity were found to be met through examination of scatterplots. Pearson correlations were calculated between all predictor variables to test for multicollinearity. No extremely high correlations i.e. 0.9, were identified, suggesting that all items were suitable for inclusion in further analyses.[83] The Shapiro-Wilk test at $p>0.05$ was used to test for normality based on recommendations by [83] for small sample sizes.

Independent t-tests were used to explore gender differences. Correlational analysis was used to examine how the demographic (age) and clinical variables (severity of pain, pain duration and distress) related to self-warmth, self-coldness, self-esteem and pain outcomes (quality of life and disability) to establish what variables to control for in the hierarchical regression analyses. Correlational analyses were also run to determine the relationship between self-warmth, self-coldness, self-esteem and the outcome variables (quality of life and disability). Following this hierarchical regression analyses using forced entry of three blocks were planned with self-warmth, self-coldness and self-esteem as the predictor variables and disability and quality of life as the dependent variables while controlling for gender, pain severity and distress.

2.3 Results

2.3.1 Descriptive Data

Table 2.1 presents the difference between males and females in relation to mean and standard deviation (SD) for each measure completed in the study. For the total samples self-esteem scores produced a mean of 26 (SD 7.2). Average scores on the SCS subscales were 35.34 (SD= 11.68) for self-warmth and 43.78 (SD=11.65) for self-coldness. Mean scores on the HADS subscales were 11.56 (4.87) for anxiety and 9.88 (4.67) for depression and when classified according to clinical thresholds produced, 70% (N=42) were in the clinical range of symptoms for anxiety and 80% (N=48) for depression. Mean scores of 63.67 (SD=18.58) and 93.12 (SD=26.61) were obtained for quality of life and disability respectively.

2.3.2 Control Variables

Gender has been shown to be a significant influence on many aspects of life for adults with chronic pain.[84] Preliminary two-tailed t-tests were conducted to compare scores of males (N=21) and females (N=39) on each measure (see Table 2). Females reported higher quality of life with the Cohen's d indicating a medium effect size (0.7). No significant gender differences were found for levels of distress, pain severity, self-esteem, self-warmth and self-coldness. Cohen's d indicated small effect sizes for these non-significant mean differences. Significant gender differences found in relation to quality of life indicated that gender should be controlled for in the hierarchical regression where quality of life was the dependent variable.

Table 2.1 Mean differences between genders on outcome measure scores

Outcome Measures	Male Mean (SD) N=21	Female Mean (SD) N=39	Mean Difference	t	P-value	95% Confidence Interval Lower	Upper
BPI-SF Pain Severity Subscale	6.38 (1.6)	6.50 (1.6)	.119	.28	.79	-.76	.99
HADS TOTAL SCORE	23.95 (7.3)	20.10 (9.0)	3.85	-1.79	.08	-8.18	.48
Rosenberg Self-Esteem Total Score	25.38 (6.1)	26.48 (7.8)	1.20	.60	.55	-2.56	4.76
Self-Warmth	34.52 (12.8)	35.77 (11.2)	1.25	.38	.71	-5.48	7.98
Self-Coldness	43.79 (12.0)	43.77 (11.6)	-.02	-.00	.99	-6.52	6.49
Quality of Life Total Score	55.61 (17.3)	68.00 (18.0)	12.39	2.61	.01*	2.80	21.98
Pain Disability Questionnaire Total Score	101.92 (22.2)	88.34 (27.8)	-13.54	-1.92	.06	-27.63	.56

*Gender difference significant at the level of p<.05

95% bias corrected and accelerated confidence intervals based on 1000 bootstrap samples

*Levene test significant

2.3.3 Correlation Analysis

Table 2.2 presents the results of the Pearson's correlations among the measures of self-warmth, self-coldness, self-esteem, severity of pain, quality of life, distress and disability. All variables were significantly correlated in the predicted directions. Consideration was given to the inclusion of age and duration of pain as control variables within the regression analysis. However, age did not significantly correlate with either quality of life [CI-.14,.39] or disability [CI-.5,.08] and pain duration did not significantly correlate with either quality of life [CI-.19, .33] or disability [CI-.31,.29].

2.3.4 Regression Analysis

A four stage hierarchical regression was conducted with quality of life as the dependent variable, to explore the independent effect of self-esteem, self-warmth and self-coldness on quality of life while controlling for gender, severity of pain and distress. Data met the assumption of independent errors (Durbin-Watson= 1.9) and multi-collinearity was not deemed to be a concern as tolerance scores ranged from .29 to .8 and variance inflation factor (VIF) scores from 1.26 to 3.48 (O'Brien, 2007). When gender was entered in step 1, it explained 8.7% of the variance in quality of life. Entering severity of pain subscale at step 2 explained an additional 13% of the variance in quality of life. HADS total score was entered in at step 3 which explained 42% of the variance in quality of life. Finally, RSES total score and the SCS subscales (self-warmth and self-coldness) were entered in at step 4, explaining 8% of the variance in quality of life. The model as a whole explained 70.6% of the variance in quality of life. Four variables made a statistically significant contribution to this model. In order of highest beta values: HADS total, self-warmth subscale, and BPI-SF pain severity. The negative coefficients indicate that higher levels of distress, and pain

severity were associated with lower rates of quality of life. The positive co-efficient indicates that higher levels of self-warmth were associated with higher rates of quality of life. Coefficients for all variables, including those with a non-significant contribution to the model, are presented in Table 2.3.

A second hierarchical regression analysis was performed to examine if self-warmth, self-coldness and self-esteem made a unique contribution to disability outcomes after pain severity, and distress were accounted for in the analysis. BPI-SF pain severity subscale was entered in step 1 and explained 18% of the variance in disability. Entering HADS total score at step 2 explained an additional 17% of the variance in disability. RSES total score and the SCS subscales self-warmth and self-coldness were entered in at step 3. RSES total score and self-compassion subscales were not significant predictors of scores on the PDQ.

Table 2.2 Pearson's correlation coefficients for correlations of key variables, age and pain duration

	1.	2.	3.	4.	5.	6.	7.	8.
1. Rosenberg Self-Esteem Score								
2. Self-Warmth	.482**							
3. Self-Coldness	-.600**	-.435**						
4. HADS Total	-.661**	-.485**	.617**					
5. Quality of Life Scale	.584**	.603**	-.496**	-.786**				
6. Pain Disability Questionnaire	-.519**	-.349**	.398**	.538**	-.649**			
7. BPI-SF Severity Subscale	-.281*	-.015	.162	.336**	-.344**	.436**		
8. Age	.235*	.227*	-.150	-.261*	.124	-.214	-.056	
9. Pain Duration	.012	.039	-.346**	-.231*	.083	-.038	-.118	.294*

Based on 2000 bootstrap samples

** Correlation is significant at the 0.01 level (one-tailed), * Correlation is significant at 0.05 level (one-tailed)

Table 2.3 Summary of Hierarchical Regression to predict quality of life

Variable	β	95% CI		B	t	p-value	R	R^2	Δ R^2
		Lower	Upper	standardised					
Step 1							.32	.10	.09
Gender	-12.39	-22.01	-2.77	-.32	-2.58	.01			
Step 2							.48	.23	.20
Gender	-12.89	-21.89	-3.89	-.33	-2.87	.01			
BPI-SF Pain Severity	-4.17	-6.91	-1.44	-.36	-3.06	.00			
Step 3							.81	.65	.63
Gender	-6.64	-12.93	-0.35	-.17	-2.11	.04			
BPI-SF Pain Severity	-1.30	-3.28	0.68	-.11	-1.31	.19			
HADS Total	-1.53	-1.91	-1.16	-.71	-8.25	<.00			
Step 4							.86	.74	.71
Gender	-7.63	-13.37	-1.89	-.20	-2.67	.01			
BPI-SF Pain Severity	-1.96	-3.79	-0.13	-.17	-2.15	.04			
HADS Total	-1.10	-1.59	-0.62	-.51	-4.59	<.00			
Self-Warmth	.528	.25	.80	.33	3.88	<.00			
Self-Coldness	.013	-30	.32	.01	.08	.93			
RSES	.075	-.46	.61	.03	.28	.78			

95% bias corrected and accelerated confidence intervals based on 1000 bootstrap sample

Table 2.4 Summary of Hierarchical Regression to predict pain disability

Variable		β	95% CI		B	t	p-value	R	R^2	Δ R^2
			Lower	Upper	standardised					
Step 1								.44	.19	.18
BPI-SF Severity	Pain	7.32	3.34	11.29	.44	3.69	<.00			
Step 2								.60	.36	.34
BPI-SF Severity	Pain	4.82	1.05	8.60	.29	2.56	.01			
HADS Total		1.36	.668	2.06	.44	3.93	<.00			
Step 3								.64	.41	.36
BPI-SF Severity	Pain	4.96	1.12	8.79	.30	2.59	.01			
HADS Total		0.67	-0.30	1.65	.22	1.38	.17			
Self-Warmth		-0.27	-0.85	.30	-.12	-.95	.35			
Self-Coldness		0.08	-0.57	.73	.04	.25	.80			
RSES		-0.79	-1.9	.34	-.21	-1.4	.17			

95% bias corrected and accelerated confidence intervals based on 1000 bootstrap samples

2.4 Discussion

This cross sectional study aimed to explore the role of self-warmth, self-coldness and self-esteem as predictors of quality of life and disability in a chronic pain sample. The results of the study will now be considered in relation to the initially outlined aims and hypotheses. Results showed that participants' levels of self-esteem,[85] pain severity,[62] disability,[74] and distress [86] were in line with previous studies using a chronic pain sample. Quality of life was slightly lower in this study than in previous studies [77,87] and it was not possible to compare the self-warmth and self-coldness subscales as they have not been specifically assessed in a chronic pain sample. Mental health symptoms were at clinical level for 77% of the sample, which is consistent with other studies indicating elevated mental health difficulties in a chronic pain population.[88] Overall these scores suggest that the study sample was representative of a chronic pain population. One potential reason for the lower overall mean levels of quality of life in this study was the significant gender difference between male and females on this measure. Gender differences on levels of quality of life in a chronic pain sample remain inconclusive as a number of studies have found males to have higher quality of life [89] while others [87] did not confirm any significant differences. Rustoen[90] reported similar results to this study where they found that females reported higher quality of life compared to males. One possible explanation for higher quality of life scores in women in this sample may be that men and women cope differently with chronic pain [91]. While men tend to use behavioural distraction and problem-focused tactics to manage pain, women tend to use a range of coping techniques including social support, positive self-statements, emotion-focused techniques, cognitive reinterpretation, and attentional focus.[92]

Correlation analyses revealed that higher self-esteem, higher self-warmth and lower self-coldness were related to lower levels of distress, lower disability and better quality of life.[60,38] It was found that age was significantly related to higher self-esteem, self-warmth, and lower distress. This is in line with other studies which suggest that self-compassion on well-being has been shown to be more beneficial to middle-aged adult than those in early adulthood.[93] It may be that an understanding of common humanity increases with age.[17]

The significant relationship between higher pain severity, higher distress, higher disability and lower quality of life are consistent with the results of previous research.[6,12] The significant relationships found within this study were in contrast to previous findings in a chronic illness group whereby self-compassion and self-esteem did not correlate significantly with lower disability.[52] Our findings indicate that having a salient source of positive self-regard and an ability to be kind to oneself is likely to promote positive adaptation when faced with adversity. Previous literature has reported the strong correlation between self-esteem and self-compassion, suggesting that the two constructs are not psychologically distinct. This study found that while self-coldness strongly correlated (-.6) with self-esteem, self-warmth only demonstrated a medium correlation (.42) with self-esteem. Muris et al. (in press) [94] reported a similar correlation between self-warmth and self-esteem (.44). They noted that common humanity which is a component of this subscale did not correlate significantly with global self-esteem, possibly because self-esteem is more concerned with comparing oneself to others rather than feeling connected to others. Nevertheless, the correlation between self-warmth, self-coldness and self-esteem were in keeping with what has been reported in the literature

[35] and the magnitude of the inter-correlations demonstrate that self-warmth, self-coldness and self-esteem appear to be distinct but related to aspects of personal identity. [95]

Hierarchical regression revealed that self-warmth was a significant predictor of quality of life after controlling for gender, pain severity and distress. Self-coldness was not found to be a significant predictor for quality of life. These findings were in line with previous research carried out among patients with chronic illness and cancer.[12] These studies found that self-warmth was the only predictor for quality of life among cancer patients. However, Pinto-Gouveia et al., 2013 also reported that self-coldness explained the majority of the variance for quality of life in patients with chronic illness.[12] It would be expected that the results of this study should be more in line with the chronic illness patient group rather than the cancer patient group in Pinto-Gouveia et al. (2013) study.[12] However, their study did not contain a pain severity measure and therefore it may be that the cancer patients experienced more pain severity [96] than the chronic illness group, which might account for the similarities between the chronic pain sample in the present study and the cancer group in Pinto-Gouveau et al. (2013) study.[12] These findings seem to support the theory that the way self-compassion enhances positive wellbeing is via the increased self-kindness, common humanity, and mindfulness associated with a compassionate mind state. It must be noted that distress was the more important predictor of quality of life than the other predictors in the model. Distress was added to the forced entry regression before self-coldness and it is likely that this reduced the predictive power of self-coldness in this model. This study and previous studies have reported significantly high correlations between self-coldness and distress compared with self-warmth and distress. This finding offers further support to Muris et al (2016) argument

that although the protective influence of self-warmth exists in relation to psychopathology, the effect is likely to be boosted when self-coldness is also included.[24]

The hypothesis that self-esteem would be a significant predictor for quality of life was not supported in this study. The finding may be a result of the measure used for quality of life in that the QOLS does not contain subscales separating out physical and psychological components of quality of life like the SF-36.[97] In a study looking at multiple sclerosis, it was found that self-esteem only explained the variance on the Mental Component Scale (MCS) rather than the Physical Component Scale (PCS) of the SF-36.[42] Self-esteem thus seems to be important in MCS, which is in line with previous findings in other chronic conditions.[43,85,98] Many studies used the SF-36 in medical setting for chronic illness or chronic pain and it may be that self-esteem is more likely to predict quality of life because self-esteem is a psychological variable and MCS may be considered predominantly of psychological or emotional nature. While self-esteem was not a predictor for quality of life, our findings support previous findings which reported that self-compassion would account for the unique variance in outcome variables when controlling for self-esteem. This study adds to the evidence base in that chronic pain is a more adverse life experience than the examples (e.g. poor grade on a test) that were used in other research when examining the differences between self-esteem and self-compassion in relation to psychological well-being.[51]

The findings that neither self-warmth, self-coldness nor self-esteem were significant predictors of physical disability were contrary to our hypotheses that self-warmth or self-coldness would be a stronger predictor than self-esteem for disability. In contrast other research demonstrated that self-warmth predicted better adjustment to physical disability.[60]

It must be noted that Wren et al. [60] recruited participants who had a >30 BMI, therefore it may be that self-warmth has the potential to act as a buffer against the mental and global health detriments of self-stigma which relate to disability in overweight and obesity [99] rather than chronic pain. Our study replicated findings from Hoge et al [100] in that they found that self-compassion correlated with disability in a group of people suffering from generalised anxiety disorder, however, self-compassion was not a significant predictor of disability. Instead they found that the non-judgment of inner experience component of mindfulness contributed to lower disability. This has also been reported in the chronic pain literature [32] and it may be useful to further explore the subcomponents of self-warmth (common humanity, self-kindness and mindfulness) to explore which components correlate and predict a relationship with lower disability in chronic pain.

2.4.1 Clinical Implications

The current findings have important implications for clinicians working with this population. Clinicians should assess psychological constructs such as self-warmth and target interventions to promote this type of protective processes in an attempt to improve overall quality of life in people with chronic pain. There is rising evidence that self-warmth can be increased with practice [101] with many interventions having been proposed for people with chronic pain; loving kindness meditation;[102] compassion meditation;[103] positive psychology techniques;[104] and mindfulness.[32] There is also research to suggest that third wave interventions such as Dialectical Behaviour Therapy (DBT)[105] and Acceptance and Commitment Therapy (ACT)[106] may be useful due to their emphasis on mindfulness and concepts similar to over-identification i.e. cognitive defusion.[107] In keeping with recent government strategies which

state that “good mental health is not potentiated solely by the absence of mental ill health but the presence of positive mental health factors”,[108] it is suggested that increased knowledge on the role of self-compassion in adult mental health, particularly chronic pain settings, may provide and promote an alternative way to conceptualise chronic pain difficulties.

2.4.2 Strengths and Limitations

To the author’s knowledge, this study is the first to explore the role of self-warmth, self-coldness and self-esteem as predictors of quality of life and disability in a chronic pain sample. The SCS is currently the most widely used measure of self-compassion, however concerns have been raised in relation to its underlying structure. Costa et al. (2015) did not replicate evidence for an overarching construct of self-compassion, suggesting that a two factor structure model is more appropriate.[59] The present study used a two factor model to further investigate its utility in a clinical population. In addition, the study used standardised validated psychometrics with psychometric properties demonstrated both in previous research and replicated with the current sample. The sample was recruited from several sites in Scotland e.g. NHS and self-management groups, which may help to reduce biased results towards a specific demographic. Although a larger sample recruited from the community to increase the generalisability of findings would have helped to increase reliability of the study.

The sample size was small due to a low response rate, however this is consistent with a postal survey response in a chronic illness group.[52] The method for data collection may have created a sample bias where by individuals with greater functional disability were unable to

participate. The cross-sectional design prevents causal inference, therefore a suggestion for future research could conduct controlled studies in a laboratory setting where self-compassion could be manipulated and the effects on key outcomes systematically assessed (e.g., severity of pain, distress, quality of life, disability). In addition, the present study relied on self-report measures. Future studies investigating the relationship between self-compassion and pain adjustment should consider integrating self-report measures with direct measures, such as functional performance and structured clinical interviews.

The results of the current study indicate a need for further research particularly in relation to longitudinal and experimental studies, explicitly testing causal chains such as those proposed in this study. This was the first study to explore self-warmth, self-coldness and self-esteem as predictors in a chronic pain sample, replication with a larger sample is necessary to strengthen the conclusion drawn and to ensure generalisability.

2.4.4 Conclusion

The current study expands the literature by demonstrating self-warmth as a unique predictor of quality of life when distress, severity of pain and gender were controlled for in a chronic pain population. It was also found that neither, self-warmth, self-coldness or self-esteem were unique predictors of disability when controlling for distress and severity of pain. The findings suggest that interventions which may increase self-warmth such as Compassionate Mind Training [101] would be an effective treatment in addressing poor quality of life for people with chronic pain.

2.5 References

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Appendix A-Full Author Guidelines for Journal of Contextual Behaviour

JOURNAL OF CONTEXTUAL BEHAVIORAL SCIENCE

ELSEVIER

AUTHOR INFORMATION PACK

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DESCRIPTION

The *Journal of Contextual Behavioral Science* is the official journal of the Association for Contextual Behavioral Science (ACBS).

Contextual Behavioral Science is a systematic and pragmatic approach to the understanding of **behavior**, the solution of human problems, and the promotion of human growth and development. Contextual Behavioral Science uses functional principles and theories to analyze and modify action embedded in its historical and situational context. The goal is to predict and influence behavior, with precision, scope, and depth, across all behavioral domains and all levels of analysis, so as to help create a **behavioral science** that is more adequate to the challenge of the human condition.

JCBS welcomes **contextual behavioral analyses** of phenomena that are relevant to the aims and scope of the society's mission, which is to change behavior at an individual or cultural level, to alleviate human suffering, and to advance human wellbeing. *JCBS* is also a strategic approach to the analysis of human behavior that proposes the need for a multi-level (e.g. social factors, neurological factors, behavioral factors) and multi-method (e.g., time series analyses, cross-sectional, experimental...) exploration of contextual and manipulable variables relevant to the prediction and influence of **human behavior**. In addition it places a strong emphasis in theory development and the promotion of effective practices that link back to scientific principles.

The journal considers papers relevant to a contextual behavioral approach include empirical studies (without topical restriction - e.g., clinical psychology, psychopathology, education, organizational psychology, etc.), reviews (systematic reviews and meta-analyses are preferred), and conceptual and philosophical papers on contextual behavioral science. We are particularly interested in papers emphasizing the study of core behavioral processes that are relevant to a broad range of human problems, and thus not limited to certain populations. Conceptual papers selected for publication may address a broad range of topics but generally will focus on contextual and functional variables or the philosophical analysis of contextual behavioral science. Papers that challenge a contextual behavioral science approach are always welcome. Papers bridging different approaches (e.g., connecting behavioral approaches with cognitive views; or neurocognitive psychology; or evolutionary science) are particularly encouraged.

The journal publishes papers written by researchers, practitioners, and theoreticians from different intellectual traditions. What is distinctive is not a narrowly defined theory or set of applied methods but whether the methodology, conceptualization, or strategy employed is relevant to a contextual behavioral approach.

GUIDE FOR AUTHORS

Types of article

All manuscripts must clearly and explicitly be of relevance to CBS. You may find the JCBS article "Contextual Behavioral Science: creating a science more adequate to the challenge of the human condition" helpful in assessing whether your manuscript is likely to be of interest to readers of this journal.

Articles should fall into one of seven categories:
1. Empirical research (up to 6000 words)
2. Brief empirical reports (up to 3000 words)
3. Review articles (up to 10,000 words)
4. Conceptual articles (up to 6000 words)
5. In practice (up to 3000 words)
6. Practical innovations (up to 3000 words)
7. Professional interest briefs (up to 3000 words)

Word limits exclude references, tables and figures but include the abstract

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2. Brief empirical reports. Manuscripts in this section may report preliminary, provocative or replicated results. Empirically sound methodology and adequate power remain important considerations.

3. Review articles. Manuscripts reviewing a wide range of topics are encouraged as long as their content is directly relevant to CBS. Systematic reviews and meta-analyses are particularly welcome. Authors are advised to consult relevant MARS (www.apa.org/pubs/authors/jars.pdf) and PRISMA resources (http://www.prisma-statement.org/) when preparing such manuscripts.

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5. In practice. Manuscripts in this section are designed to make CBS useful to practitioners from a wide variety of areas. Manuscripts must be written in an accessible style and should be easily understood by practitioners who are not experts in research or basic behavioral science. Manuscripts should provide both clear insights for new practitioners as well as stating the questions that remain to be answered by future research.

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Cancer Research UK. Cancer statistics reports for the UK. (2003). http://www.cancerresearchuk.org/aboutcancer/statistics/cancerstatsreport/ Accessed 13.03.03.

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- E-mail address
- Full postal address

All necessary files have been uploaded, and contain:

- Keywords
- All figure captions
- All tables (including title, description, footnotes)

Further considerations

- Manuscript has been 'spell-checked' and 'grammar-checked'
- References are in the correct format for this journal
- All references mentioned in the Reference list are cited in the text, and vice versa
- Permission has been obtained for use of copyrighted material from other sources (including the Internet)

Printed version of figures (if applicable) in color or black-and-white
• Indicate clearly whether or not color or black-and-white in print is required.
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Appendix B- Quality Rating Tool for Systematic Review

	Yes	Partial	No
Sampling: The recruitment method			
The recruitment/sampling method ensures that minimal bias is introduced (e.g. recruitment from the general population)			
The recruitment/sampling method used random sampling			
The recruitment/sampling used a convenience sample			
Validated Method for ascertaining severity of Fibromyalgia			
The psychometric properties of the outcome measure for fibromyalgia are valid and reliable in this study population			
The measure has not been validated in this population			
The measure has not undergone any psychometric evaluation, or did not used a measure to assess severity of fibromyalgia			
Power and Sample Size			
The study has a sample size large enough to detect a small to moderate effect size with the statistical power of 0.8 at an alpha level of 0.05			
The study has a sample size large enough to detect a small to moderate effect size the statistical power of 0.7 at an alpha level of 0.05			
The study has a sample size large enough to detect a small to moderate effect size with the statistical power of less than 0.7 at an alpha level of 0.05 or power was not calculable			
Appropriate Method used			
The method of statistical analysis was appropriate to the research question being asked. Confidence intervals, p-values and effect sizes are reported.			
The analysis is appropriate however the findings are not reported in sufficient detail			
The method of analysis is not appropriate to the research question and does not provide meaningful results			
Confounding variables			
Potential confounding variables are adequately recognised and a description is provided on how they are addressed in statistical analysis			
Potential confounding variables are recognised and there is recognition of a possible effect but they are not considered in statistical analysis			
Potential confounding variables are not considered			

Appendix C- Excluded Studies from Systematic Review

Studies excluded	Reasons for exclusion
Full Article Review	
Alves, 2012	No control
Amital 2014	Included both FM and Systemic sclerosis in the sample
Andrell 2014	SF—36 were z scores
Angst 2006	Needed to have had history of failed treatment to participate in the study
Aparicio 2013	Did not include SF-36 subscales
Aparicio 2014	Inclusion criteria obesity
Arranz 2012	Split FM according to BMI
Assis, 2006	No control
Atagun, 2012	Duplicate
Berfman, 2005	Did not include SF-36 subscales
Boehm, 2011	Did not include SF-36 subscales
Borsbo, 2010	Did not include SF-36 subscales
Brattberg, 2008	Had to be non-working
Brill, 2012	Did not include SD for SF-36 means
Burckhardt, 2005	Did not include SF-36 subscales
Buskila, 2000	Did not include SF-36 subscales
Campos, 2012	No control
Campos, 2013	Split FM into age cohorts
Carbonell-Baeza, 2011	Did not include SF-36 subscales
Cardona-Arias, 2014	No Controls
Castellli, 2012	No Controls
Chen, 2014	Conference abstract- unavailable
Choy, 2009	Did not include SF-36 subscales
Coster, 2008	Control group included people with pain
DaCosta, 2000	Could not access article
Danis, 2015	Abstract conference- unavailable
De Araujo	No control group
Dell'Osso, 2011	Could not access article
Dogramaci, 2009	Split FM into skin conditions
Donaldson, 2001	No Control
Glattacker, 2010	Treatment Groups
Jensen, 2009	Did not include SF-36 subscales
Jiao, 2015	Sample from a previous treatment group
Jiao, 2015	Split FM into history of abuse
Jiao, 2014	Divided into age cohorts
Kim, 2012	Split FM into BMI
Kim, 2012	FM in BMI
Kim, 2013	Same data set
Kim, 2012	Did not include SF-36 subscales
Latorre, 2013	Treatment study
Martinez, 2001	No standard deviation for the SF-36 subscales
Matsumoto, 2011	No control
Oliveiria, 2009	No control
Oncu, 2013	RA control group

Peleg, 2008	No control
Picavet, 2003	No control
Raj, 2000	No control
Rodero, 2010	No control
Romero, 2012	Treatment control
Rosenzweig, 2010	No control
Sanudo, 2011	RCT- treatment
Sanudo, 2012	RCT- same data as above
Saxe, 2009	Did not include SF-36 subscales
Schlenck, 1998	Did not include SF-36 subscales
Schlenck, 1998	Used a CBT treatment groups
Seo, 2010	Abstract Conference- unavailable
Servant, 2011	Did not include SF-36 subscales
Sigl-Erkel, 2011	RCT
Silvas, 2009	RA control
Slawsky, 2011	Used the Rand SF-36
Taggart,	No control
Theadorn, 2007	No control
Trinanes, 2015	No control
Tomas-Carus, 2009	No control
Trovato, 2010	Did not include control
Turan, 2011	No control
Uhlemann, 2007	Did not include control
Ulas, 2006	Duplicate datas
Valim, 2002	Unable to access article
Verbunt, 2008	Did not include SF-36 subdomains
Vitorino, 2006	No Control
Yilmaz, 2008	No Control
Yoshikawa, 2010	Had to meet clinical cut-off for depression
Walker, 1997	No Control
Wang, 2010	RCT-did not include subdomains
Wang, 2010	Did not include SF-36 subdomains
Wolfe, 2013	Abstract Conference- Unavailable
Wolfe, 2011	No control
Wolfe, 2005	No control
Wolfe, 2009	No control
Wolfe, 2010	No control
Wolfe, 2011	No control
Wong, 2012	RCT-did not include subdomains
Web of Science	
Efrati, 2015	Did not include SF-36 subdomains
Plazier, 2015	Did not include SF-36 subdomains
Wolfe, 2014	Did not include SF-36 subdomains
Pedro, 2012	Split FM into severity
Rombaut, 2011	Did not include SF-36 subdomains
Ubago, 2007	Did not include SF-36
Mease, 2008	Did not include SF-36 subdomains
Kaziyama, 2005	Abstract Conference- unavailable

Appendix D: Systematic Review Data Extraction Form

General Information

Date of data extraction

Author

Article Title

Citation

Type of publication (e.g. journal articles, conference abstract)

Country of origin

Study Characteristics

Aim/objectives of the study

Study design

Study inclusion criteria

Study exclusion criteria

Recruitment procedures used

Participant Characteristics

Age

Gender

Ethnicity

Socio-economic status

Mean ± SD SF-36 subscales

Mean Fibromyalgia severity

Mean depression

Co-morbidities

Disease Duration

Number of participants enrolled in study

Number of participants who provided valid data

Method

Scoring and use of SF-36

FM measure

Depression measure

Setting in which the study is conducted

Description of the controls

Outcome data/results

Additional measures/confounding variables

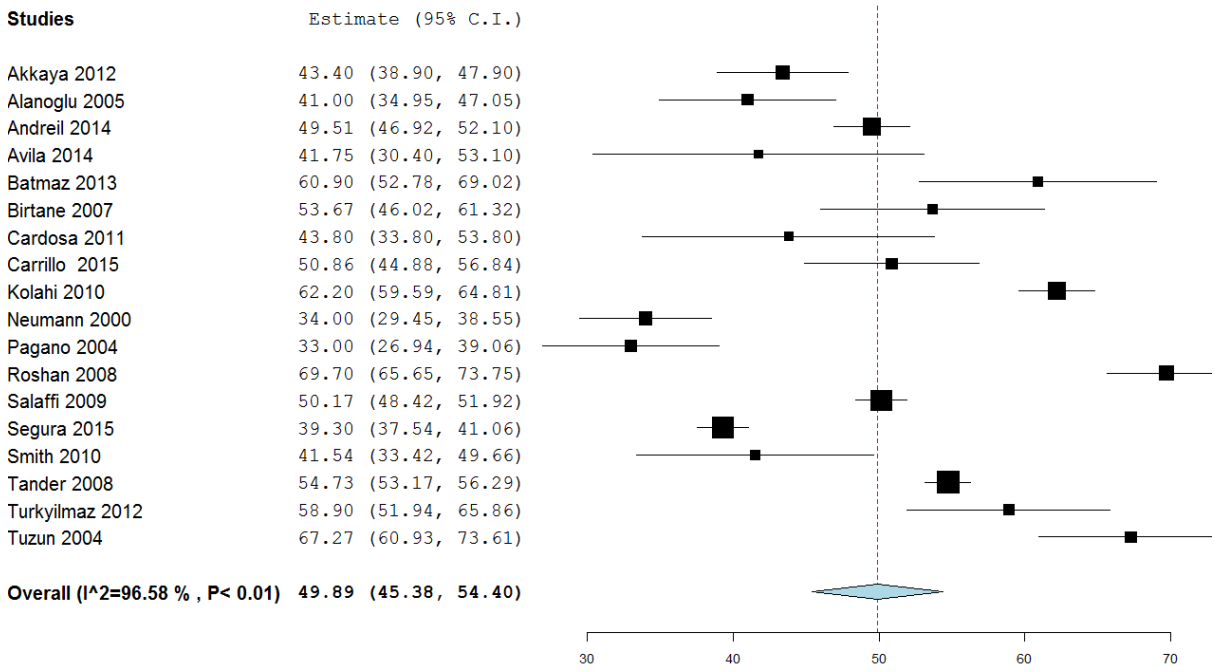
Statistical analysis used

Results of study analysis

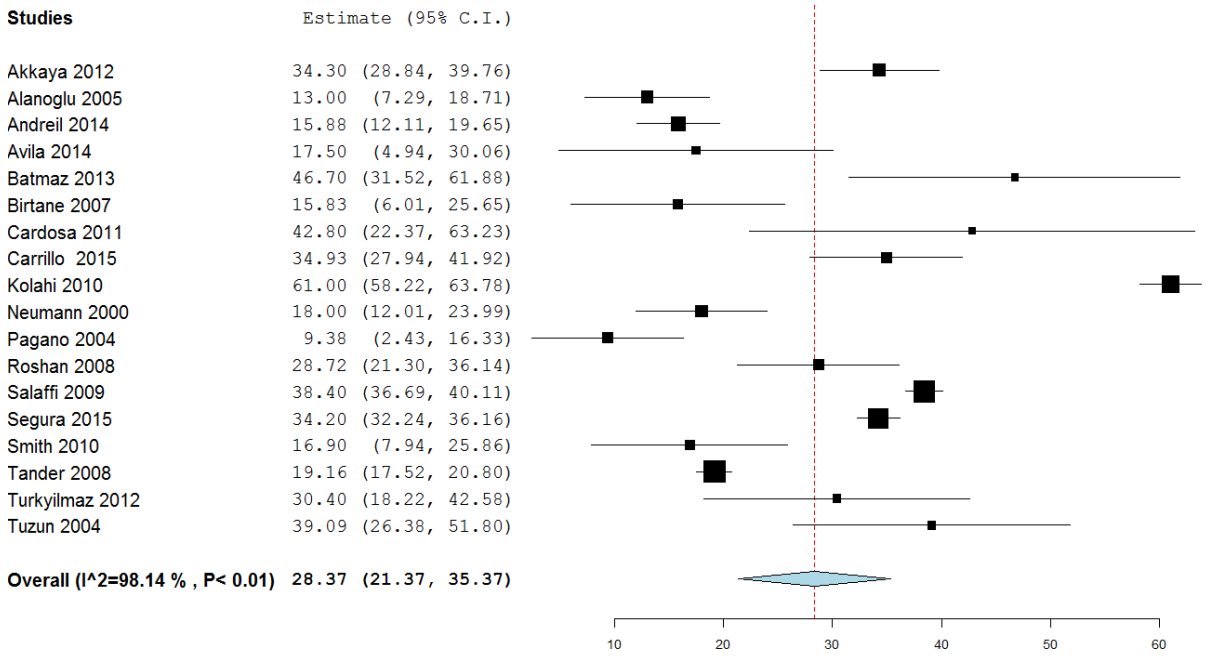
Key Findings

Appendix E- Forest Plots Meta-Analysed Pooled Mean Scores for FM for SF-36 subdomains

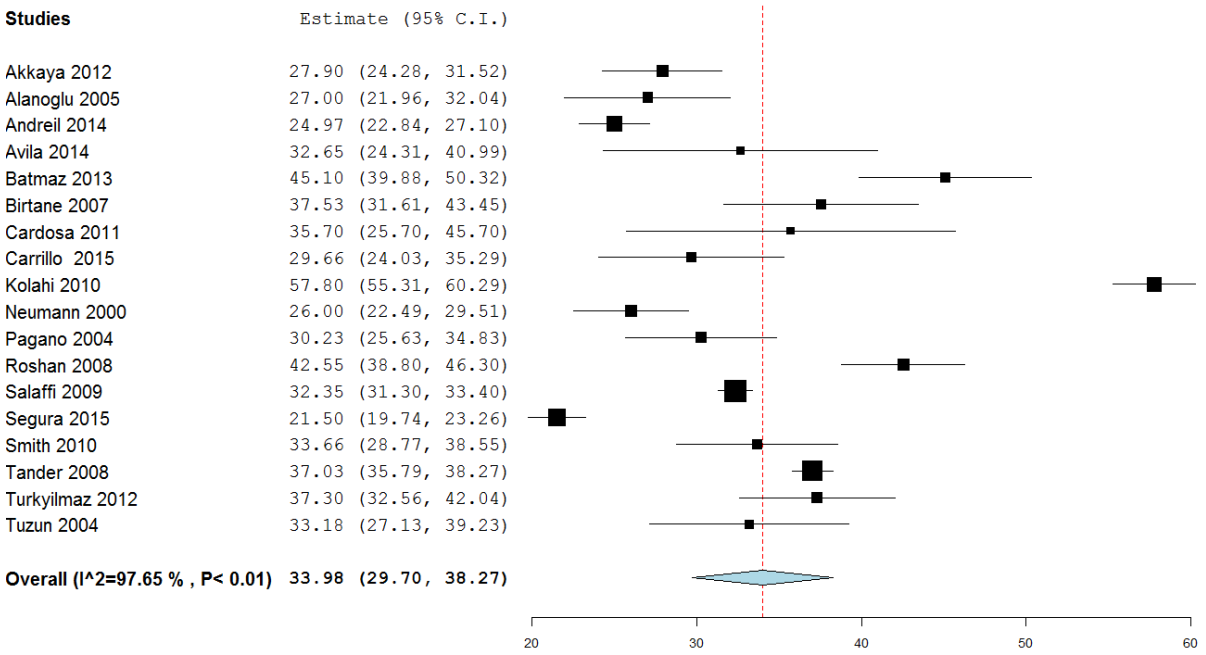
Physical Function



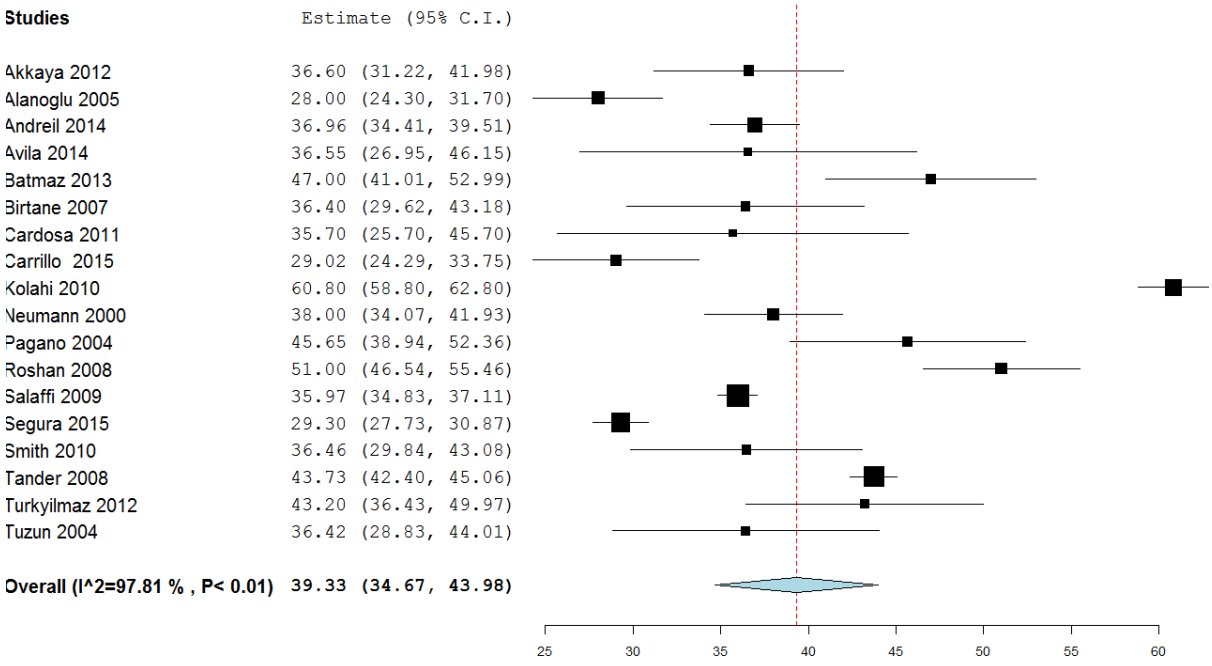
Physical Role



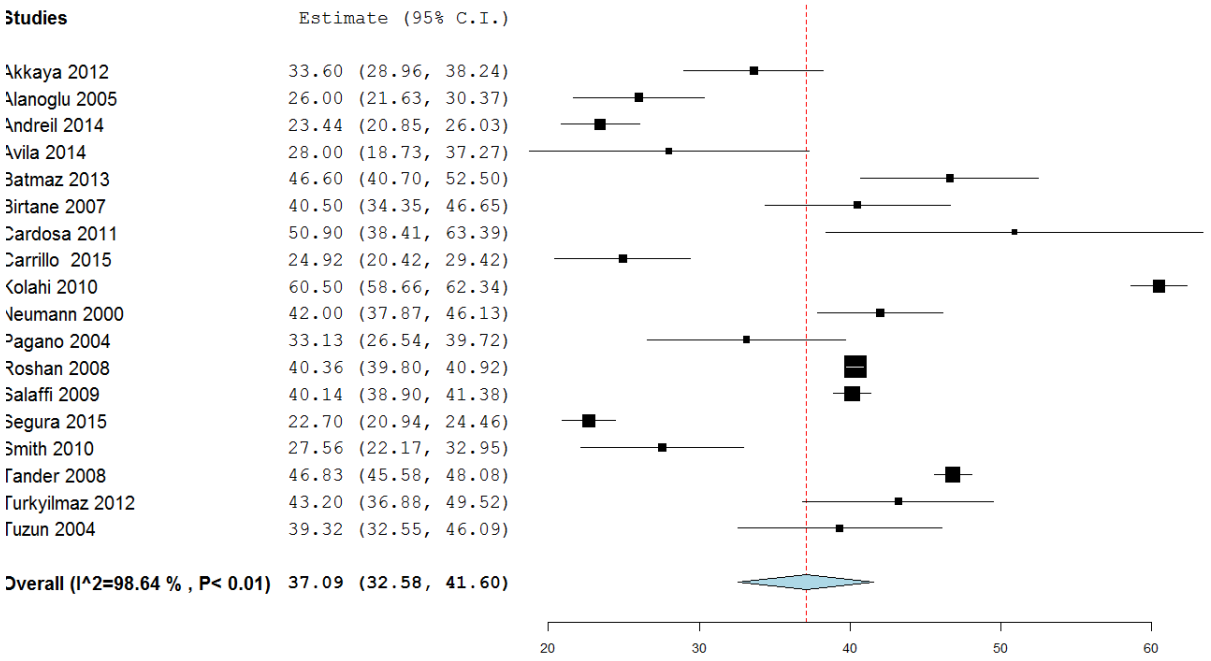
Bodily Pain



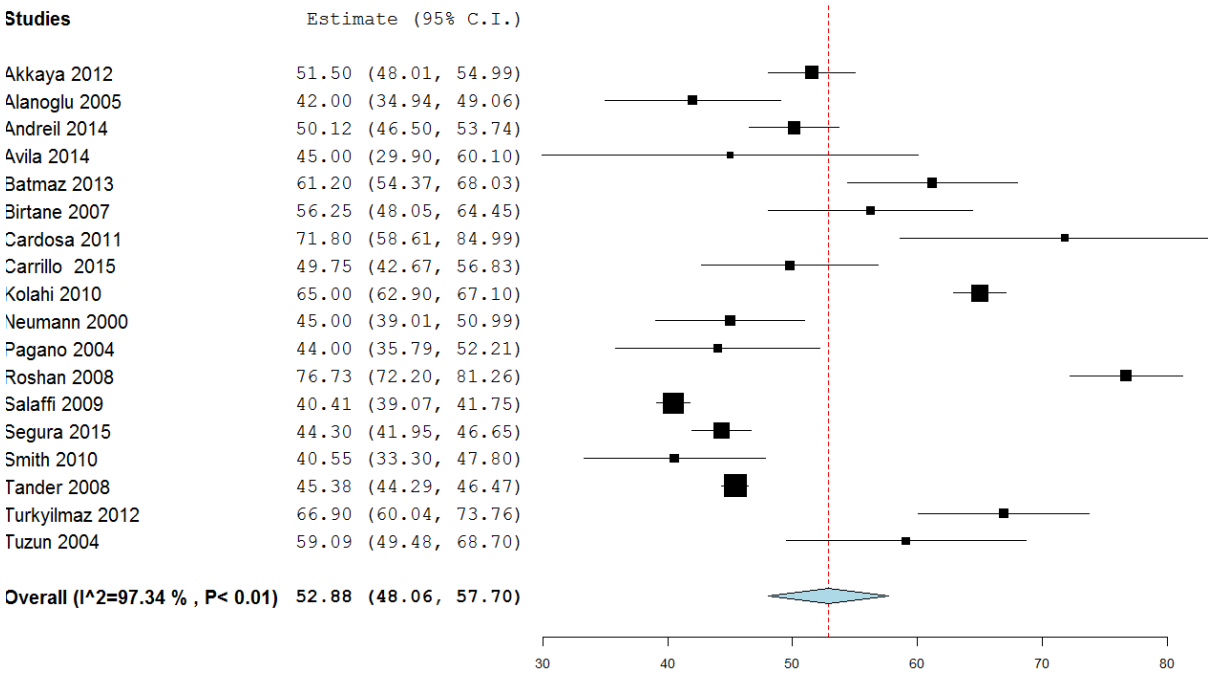
General Health



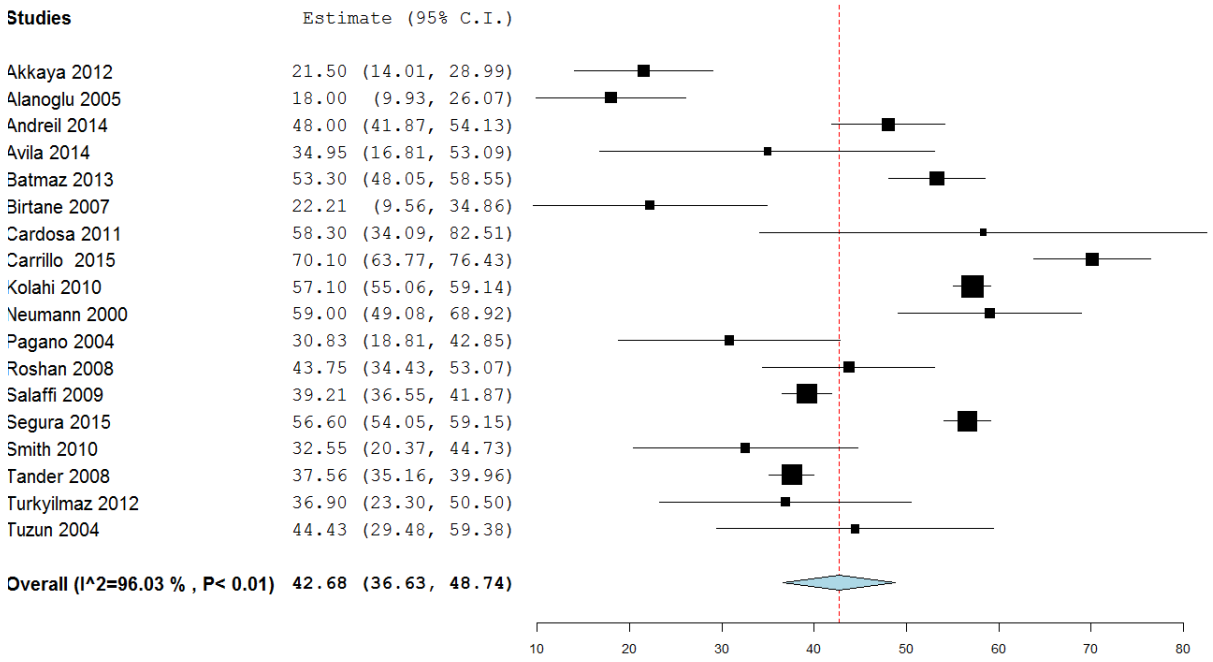
Vitality



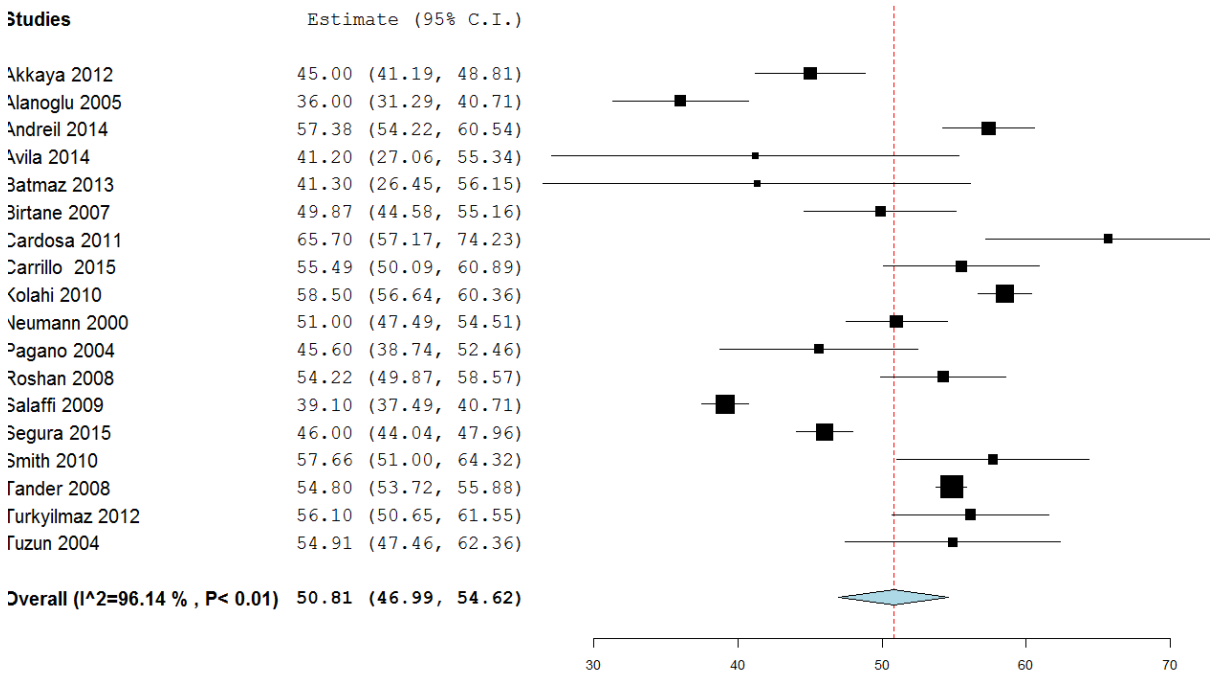
Social Functioning



Emotion Role

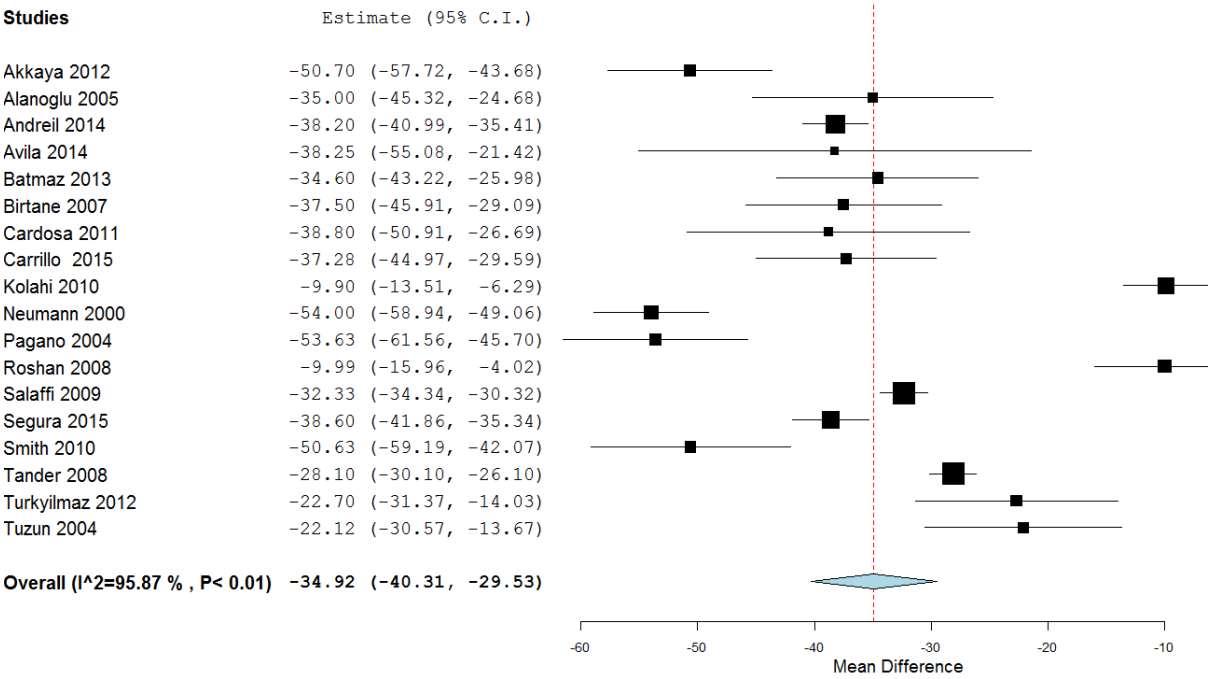


Mental Health

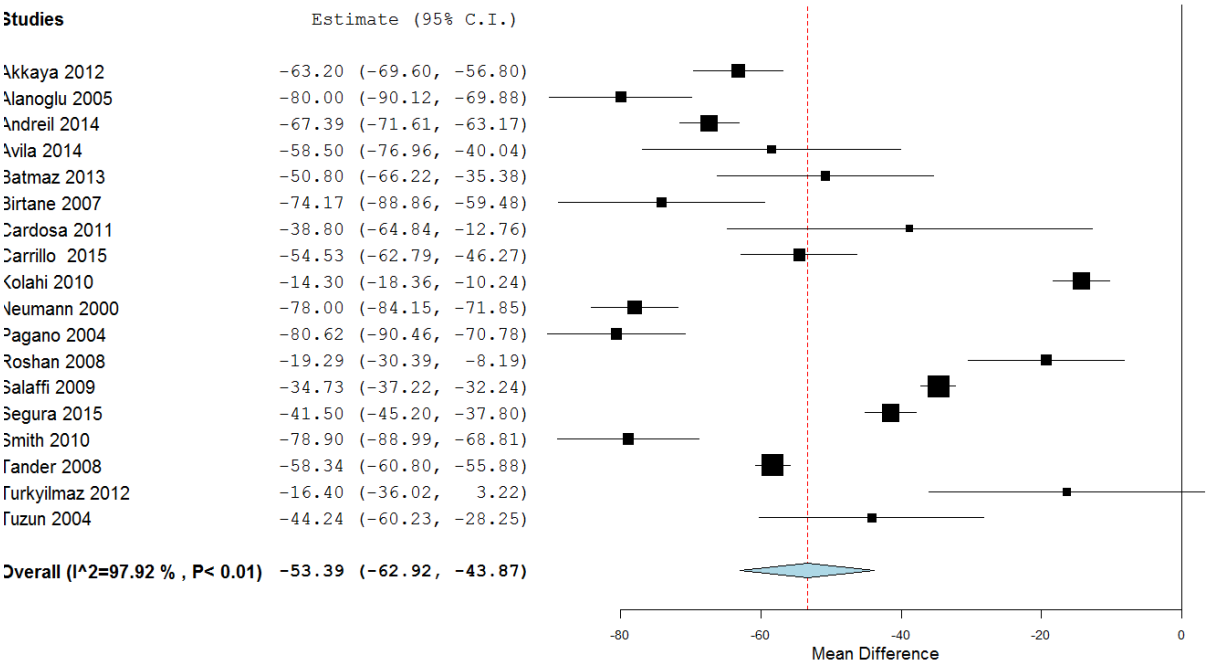


Appendix F-Difference Between Means for FM and Control Group on SF-36 Subdomains

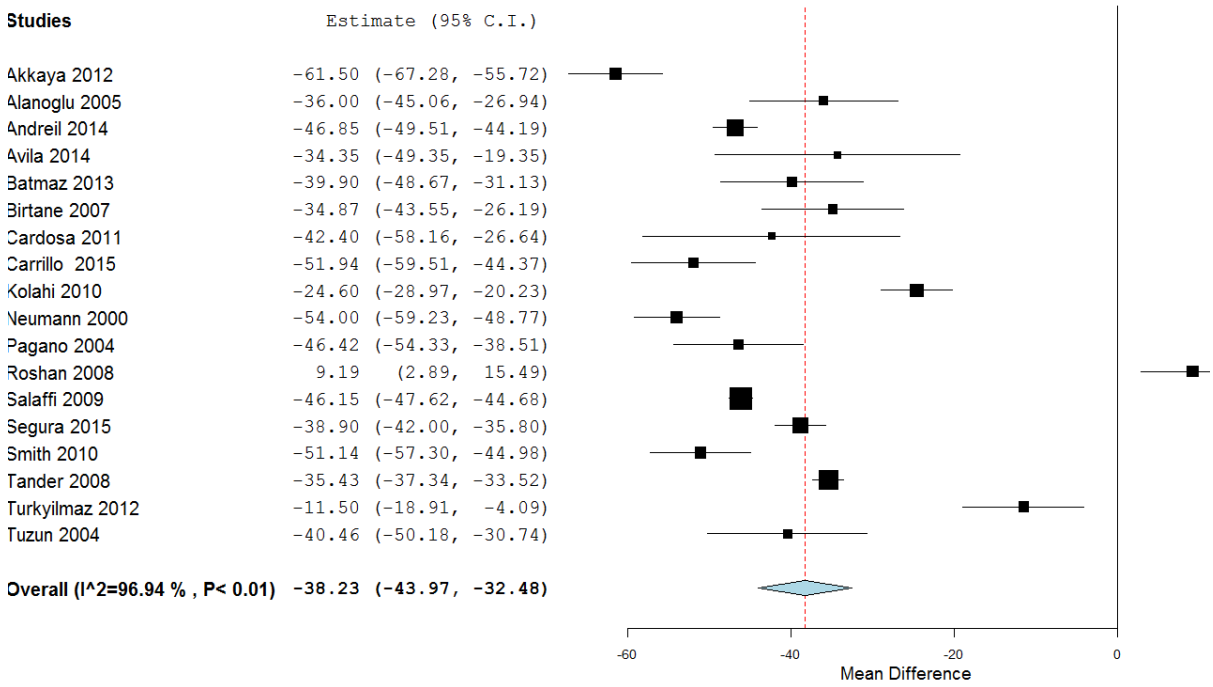
Physical Function



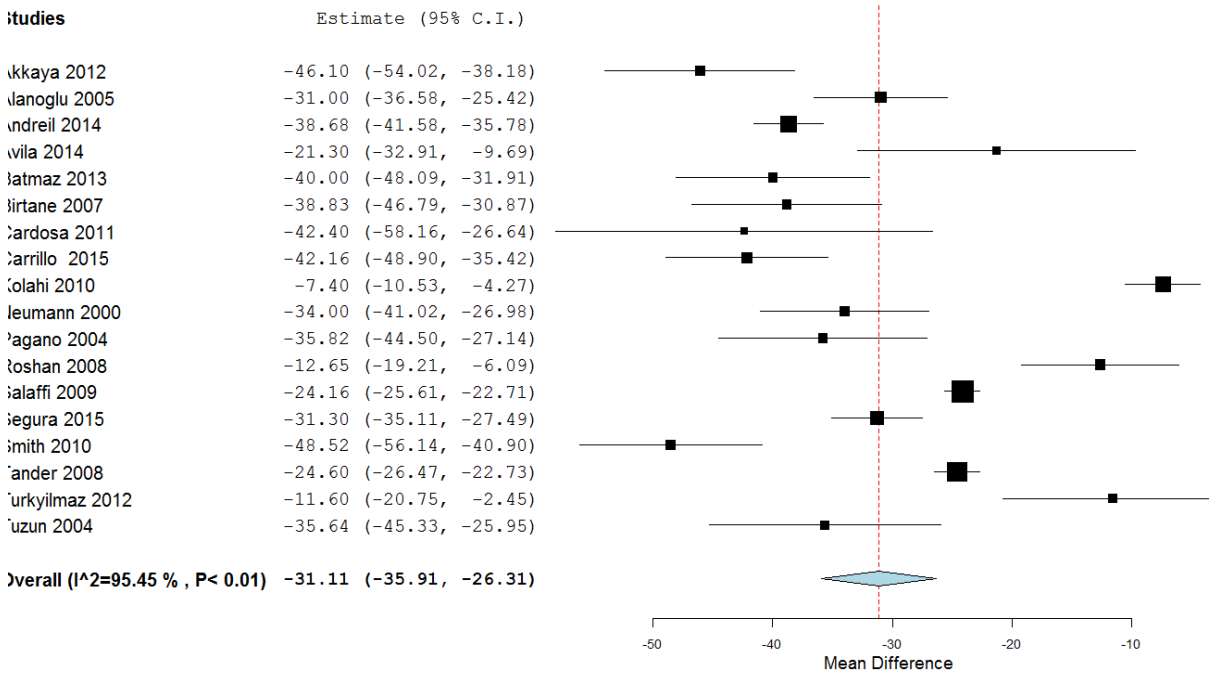
Physical Role



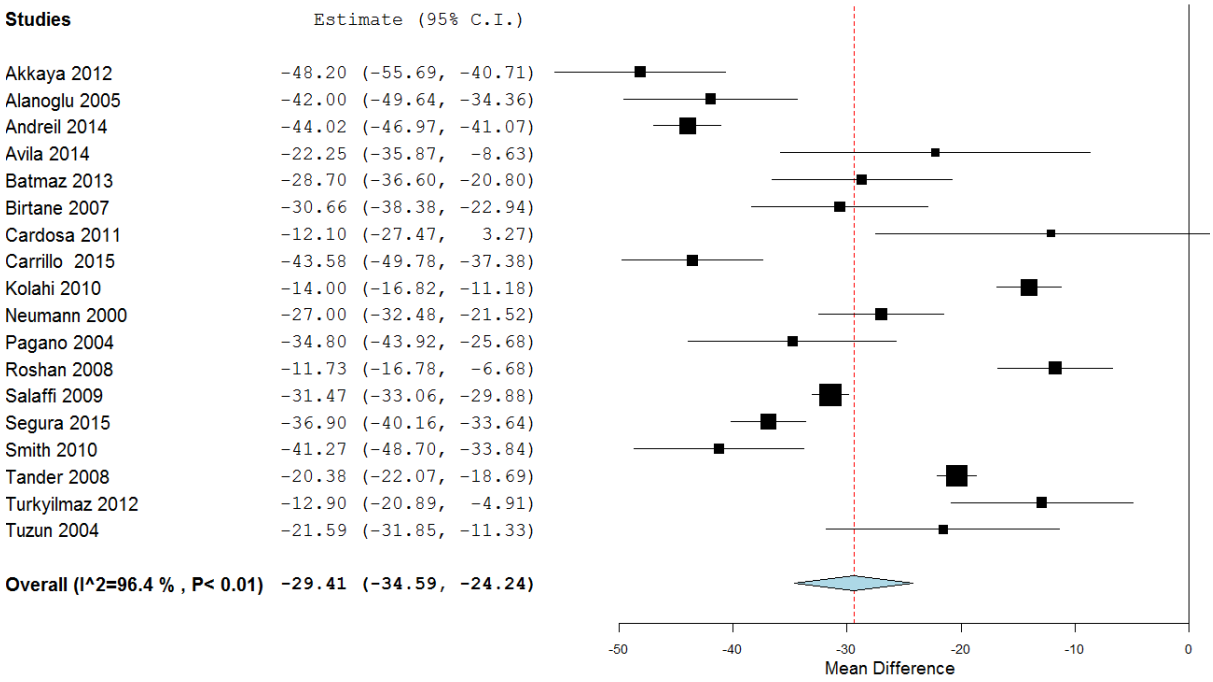
Bodily Pain



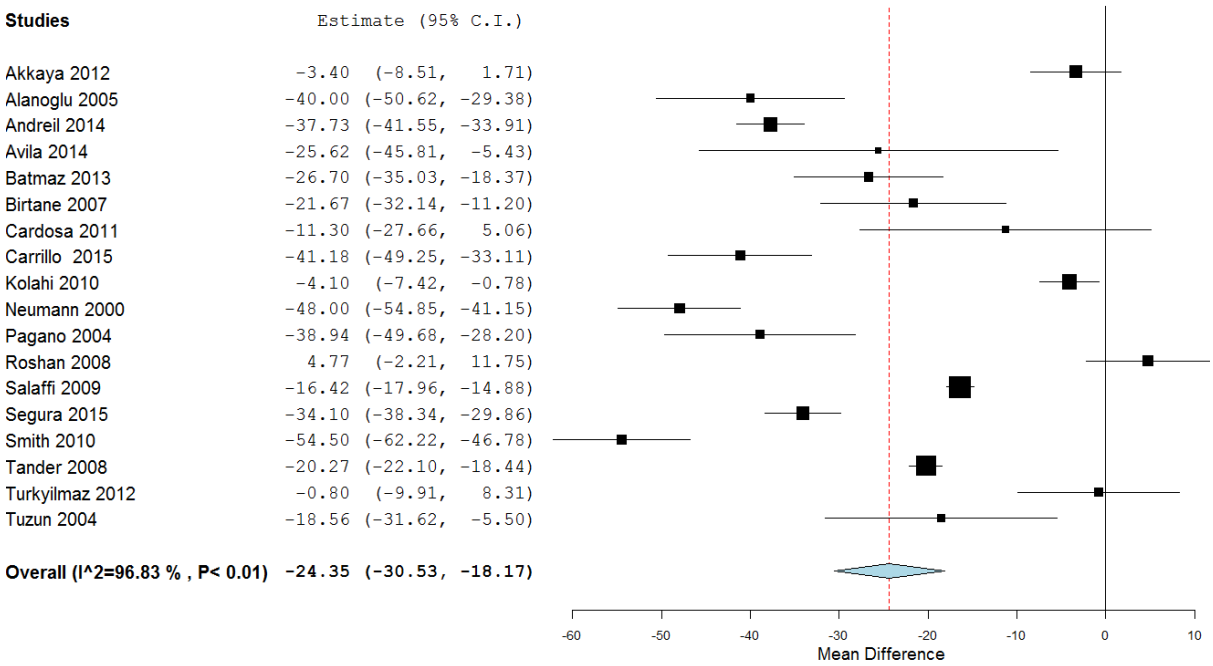
General Health



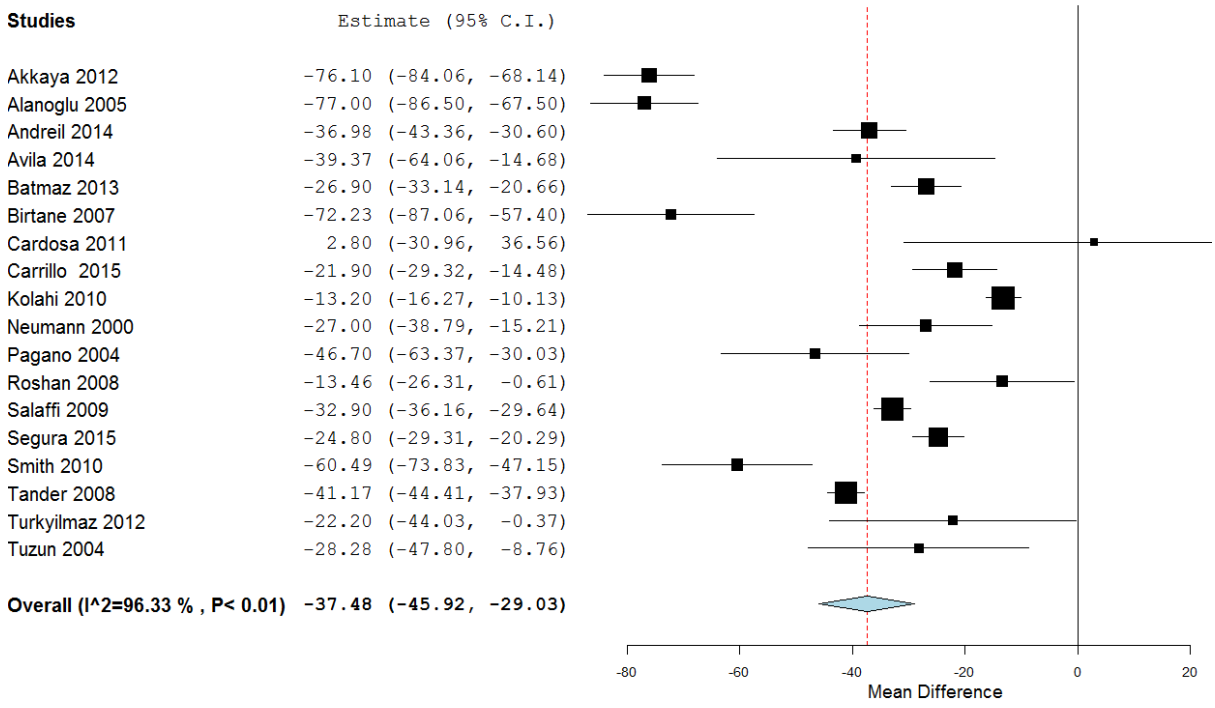
Vitality



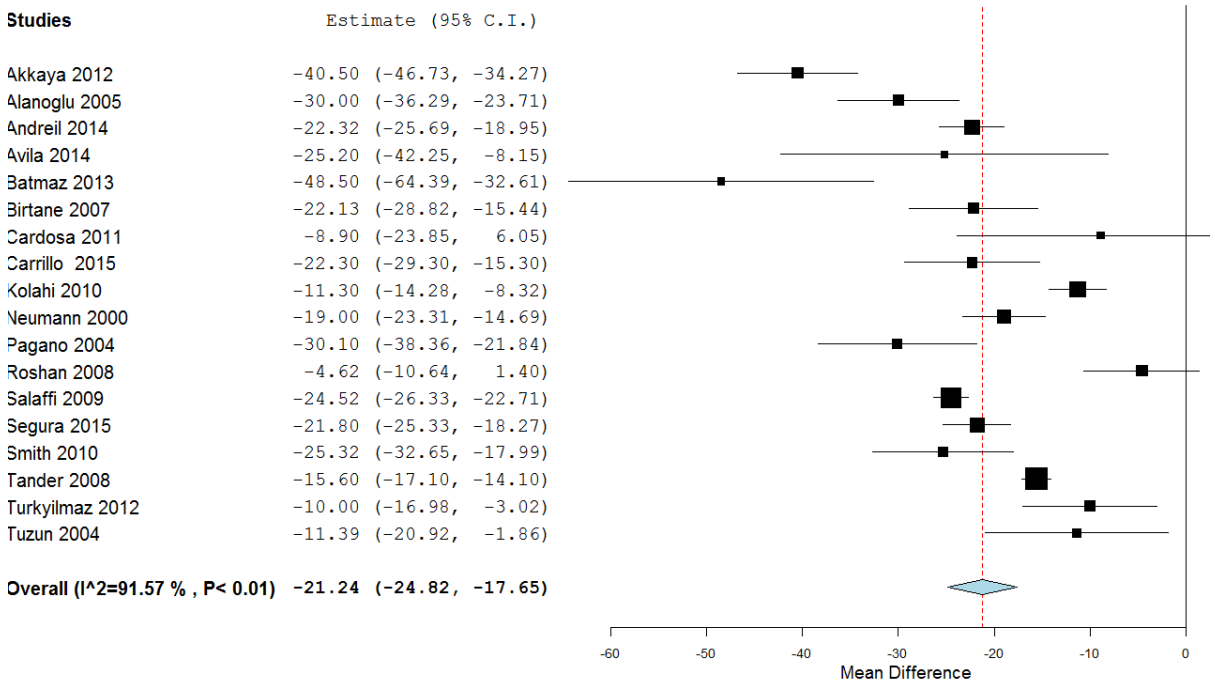
Social Functioning



Emotional Role



Mental Health



Appendix G - Sensitivity and Subgroup Analysis Table

Sensitivity Analysis	PF	PR	BP	GH	VT	SF	ER	MH
Primary Analysis	-33.9 (-40.3,-29.5) I^2= 95.9 18 studies	-53.4 (-62.9,-43.9) I^2= 97.9 18 studies	-38.2(-44.0,-32.5) I^2= 96.9 18 studies	-31.1(-35.9,-26.3) I^2= 95.5 18 studies	-29.4(-34.6,-24.2) I^2= 96.4 18 studies	-24.4(-30.5,-18.2) I^2= 96.8 18 studies	-37.5(-45.9,-29.0) I^2= 96.3 18 studies	-21.2(-24.8,-17.7) I^2= 91.6 18 studies
Excluding convenience, non-randomised or unreported sampling methods	-38.6(-43.7,-33.6) I^2= 89.5 4 Studies	-56.8(-72.1;-41.4) I^2= 98.4 4 Studies	-45.3(-49.2;-41.5) I^2= 11.1 4 Studies	-35.2(-44.6,-25.8) I^2= 97.3 4 Studies	-38.2(-45.0;-31.4) I^2= 94.9 4 Studies	-35.4(-50.7;-20.1) I^2= 98.6 4 Studies	-36.6(-45.4;-27.8) I^2= 90.0 4 Studies	-23.7(-25.1;-22.3) I^2= 0 4 Studies
Assessed Severity of FM >39	-35.8(-43.3;-28.3) I^2= 92.2 6 Studies	-50.6(-60.2;-41.0) I^2= 93.6 6 Studies	-39.2(-48.9;-29.5) I^2= 96.2 6 Studies	-29.9(-37.5;-22.2) I^2= 92.3 6 Studies	-30.9(-41.6;-20.3) I^2= 96.9 6 Studies	-20.7(-31.4;-10.00) I^2= 96.0 6 Studies	-38.1(-53.2;-23.0) I^2= 96.5 6 Studies	-22.3(-29.6;-15.0) I^2= 93.0 6 Studies
Excluding studies considered to be under power	-33.8(-43.0;-24.6) I^2= 97.9 8 Studies	-46.7(-61.2;-32.2) I^2= 98.7 8 Studies	-39.4(-49.0;-29.8) I^2= 98.4 8 Studies	-29.3(-37.6;-21.1) I^2= 97.6 8 Studies	-32.0(-40.1;-23.8) I^2= 97.8 8 Studies	-22.4(-33.0;-11.9) I^2= 98.3 8 Studies	-31.0(-42.4;-19.4) I^2= 97.2 8 Studies	-20.7(-26.1;-15.3) I^2= 94.3 8 Studies
Excluding studies that did not report findings in sufficient detail	-39.2(-45.8;-32.6) I^2= 90.3 4 Studies	-45.2(-57.2;-33.2) I^2= 95.6 4 Studies	-47.6(-55.4;-39.7) I^2= 93.7 4 Studies	-34.5(-43.4;-25.7) I^2= 92.9 4 Studies	-34.7(-41.8;-27.5) I^2= 90.6 4 Studies	-16.8(-28.9;-4.72) I^2= 96.7 4 Studies	-36.8(-57.0;-16.6) I^2= 97.7 4 Studies	-25.7(-40.0;-18.5) I^2= 90.5 4 Studies
Excluded studies that did not consider confounding variables in the analysis	-35.7(-40.9;-30.4) I^2= 93.3 12 Studies	-54.8(-64.4;-45.2) I^2= 97.1 12 Studies	-37.1(-44.6;-29.6) I^2= 97.6 12 Studies	-31.9(-36.5;-27.4) I^2= 92.7 12 Studies	-31.7(-37.3;-26.1) I^2= 95.7 12 Studies	-24.1(-30.6;-17.5) I^2= 96.3 12 Studies	-43.0(-52.6;-33.3) I^2= 96.0 12 Studies	-23.5(-28.2;-18.9) I^2= 93.3 12 Studies

Area of Origin Turkey (other)	-33.0 (-40.1;-25.8) I^2= 87.5 8 Studies	-57.6(-67.0;-48.2) I^2= 86.7 8 Studies	-37.2(-47.5;-26.9) I^2= 94.9 8 Studies	-32.4(-39.9;-25.0) I^2= 90.5 8 Studies	-29.2(-38.2;-20.2) I^2= 93.2 8 Studies	-18.4(-26.9;-9.9) I^2= 91.6 8 Studies	-50.0 (-66.1;-33.8) I^2= 96.3 8 Studies	-24.6(-33.3;-15.8) I^2= 93.8 8 Studies
Iran	-9.9(-13.0;-6.8) I^2= 0 2 Studies	-14.80(-18.7;-11.1) I^2= 0 2 Studies	-7.8(-40.9;-25.3) I^2= 98.7 2 Studies	-9.2(-14.1;-4.3) I^2= 50.1 2 Studies	-13.5(-15.9;-11.0) I^2= 0 2 Studies	-0.2(-8.8;-8.4) I^2= 80.2 2 Studies	-13.2(-16.2;-10.2) I^2= 0 2 Studies	-8.5(-15.0;-2.0) I^2= 73.7 2 Studies
America/South America	-47.6(-54.4;-40.8) I^2= 49.4 4 Studies	-68.8(-82.4;-55.1) I^2= 76.3 4 Studies	-46.3(-52.6;-40.1) I^2= 43.3 4 Studies	-37.3(-49.4;-25.3) I^2= 83.7 4 Studies	-37.3(-49.4;-25.3) I^2= 83.7 4 Studies	-33.9(-52.8;-14.9) I^2= 90.4 4 Studies	-40.5(-61.3;-19.8) I^2= 79.0 4 Studies	-24.2(-31.3;-17.1) I^2= 49.3 4 Studies
Central Europe	-38.8(-43.5;-34.0) I^2= 88.4 4 Studies	-49.4(-64.8;-34.1) I^2= 98.3 4 Studies	-45.3(-49.2;-41.3) I^2= 86.3 4 Studies	-33.8(-42.6;-25.0) I^2= 97.0 4 Studies	-38.8(-45.6;-31.9) I^2= 95.3 4 Studies	-32.1(-45.8;-18.5) I^2= 98.2 4 Studies	-29.3(-35.4;-23.3) I^2= 82.7 4 Studies	-23.6(-25.0;-22.2) I^2= 0 4 Studies

A

Appendix H - Full Author Guidelines for 'The Clinical Journal of Pain'

The Clinical Journal of Pain

Author Resources

Instructions for Authors (this page)

Copyright Transfer (PDF)

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INSTRUCTIONS FOR AUTHORS

The Clinical Journal of Pain publishes original articles in the following forms: *Clinical investigations:* Present results of original clinical research. *Case reports:* **Case reports will no longer be accepted for publication in *Clinical Journal of Pain* and thus no submission for case reports will be accepted as of June 13, 2013.** *Reviews:* Comprehensive surveys covering a broad area. They consolidate old ideas and may suggest new ones. They must provide a critique of the literature. *Special articles:* On subjects not easily classified above (e.g., articles on history, education, demography, ethics, socioeconomics, etc.). *Letters to the editor:* These may offer criticism of published material, but must be objective, constructive, and educational. A few references, a small table, or relevant illustrations may be used.

Ethical/Legal Considerations: A submitted manuscript must be an original contribution not previously published (except as an abstract or preliminary report), must not be under consideration for publication elsewhere, and, if accepted, must not be published elsewhere in similar form, in any language, without the consent of Lippincott Williams & Wilkins. Each person listed as an author is expected to have participated in the study to a significant extent. Although the editors and referees make every effort to ensure the validity of published manuscripts, the final responsibility rests with the authors, not with the Journal, its editors, or the publisher. **All manuscripts must be submitted on-line through the journal's Web site at http://cjp.edmgr.com**. See submission instructions under "On-line manuscript submission."

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figures unless they obtain written consent from the patients and submit written consent with the manuscript.

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Journal article
1. Prager J, Jacobs M, Johnson KJ. Evaluation of patients for implantable pain modalities: medical and behavioral assessment. *Clin J Pain* 2001;17:206-214.

Book chapter
2. Todd VR. Visual information analysis: frame of reference for visual perception. In: Kramer P, Hinojosa J, eds. *Frames of reference for pediatric occupational therapy*. Philadelphia: Lippincott Williams & Wilkins, 1999:205-256.

Entire book
3. Kellman RM, Marentette LJ. *Atlas of craniomaxillofacial fixation*. Philadelphia: Lippincott Williams & Wilkins, 1999.

Software
4. *Epi Info* [computer program]. Version 6. Atlanta: Centers for Disease Control and Prevention; 1994.

Online journals
5. Friedman SA. Preeclampsia: a review of the role of prostaglandins. *Obstet Gynecol* [serial online]. January 1988;71:22-37. Available from: BRS Information Technologies, McLean, VA. Accessed December 15, 1990.

Database
6. CANCERNET-PDQ [database online]. Bethesda, MD: National Cancer Institute; 1996. Updated March 29, 1996.

World Wide Web
7. Gostin LO. Drug use and HIV/AIDS [*JAMA* HIV/AIDS Web site]. June 1, 1996. Available at: http://www.ama-assn.org/special/hiv/ethics. Accessed June 26, 1997.

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- Appendix J- Permission for copyrighted questionnaires

Appendix I- Permission for Questionnaires

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symptomresearch [symptomresearch@mdanderson.org]

Sent: 29 August 2014 15:55

To: Doughty Caitriona (NHS FIFE)

Cc: symptomresearch [symptomresearch@mdanderson.org]

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Please let me know if you have any questions. Thank you for your interest in the BPI.

Regards,

Mary Samad

Appendix J- IRAS protocol for Empirical Study

The relationship between self-compassion, self-esteem and pain in a chronic pain population

Caitríona Doughty (Principal Investigator)

Version 0.5 2015-05-24

Date: 24.05.15

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Contacts

Principal Investigator

*Caitríona Doughty (Protocol author)
Trainee Clinical Psychologist
Psychology Department
Lynebank Hospital
Halbeath Rd
DUNFERMLINE
KY11 4UW

Tel: 01383 565402
caitriona.doughty@nhs.net

Clinical Supervisor

Dr Laura Keith
Clinical Psychologist
Psychology Department
Lynebank Hospital
Halbeath Rd
DUNFERMLINE
KY11 4UW

Tel: 01383 565403
lkeith@nhs.net

Research Supervisor

Dr Paul G. Morris
Lecturer of Health Psychology
Clinical Psychology

Research Supervisor

Dr Nuno Ferreiro
Lecturer
Clinical Psychology

School of Health in Social Science
Old Medical School,
Teviot Place
Edinburgh
EH8 9AG

0131 651 3956
p.g.morris@ed.ac.uk

School of Health in Social Science
Old Medical School
Teviot Place
Edinburgh
EH8 9AG

0131 650 3898
Nuno.ferreiro@ed.ac.uk

List of abbreviations

Scottish Intercollegiate Guidelines Network- SIGN; American College of Rheumatology- ACR; National Health Service- NHS; Self-Compassion Scale- SCS; Rosenberg Self-Esteem Scale- RSES; Brief Pain Inventory Short Form- BPISF; Quality of Life Scale-QOLS; Hospital Anxiety and Depression Scale- HADS.

Introduction

Chronic pain has been defined by Scottish Intercollegiate Guidelines Network (SIGN 136, 2013) as experiencing pain for at least 3 months that does not resolve with treatment. Approximately 20% of the adult European population have chronic pain (Breivik et al., 2006). Its management in the community remains generally unsatisfactory (van Hecke, Torrance & Smith, 2013). A specific chronic pain condition is fibromyalgia, which is diagnosed when an individual presents with widespread soft tissue pain (11 out of 18 paired tender points) lasting at least three months (Wolfe et al., 1990). Fibromyalgia is estimated to affect approximately 2-5% in Western Europe. Although fibromyalgia is the most common chronic widespread pain condition, it is often under diagnosed (Perrot, 2008). New criteria released by American College of Rheumatology (ACR, 2010) has proposed that focusing on the severity of characteristic fibromyalgia symptoms rather than tender point examinations may improve accuracy of diagnosis.

It is now widely accepted that psychological factors influence the relationship between chronic pain and outcomes such as disability and distress (Turk et al., 2008). Therefore, it may be beneficial in terms of managing fibromyalgia and other chronic pain conditions to explore possible psychosocial factors that contribute to the development of psychological distress in these conditions.

The association between pain and mental health symptoms in fibromyalgia were reported to be significantly higher than those in other chronic pain conditions (Gormsen et al., 2010; Taylor, Jason, & Jahn, 2003; Branco et al, 2010). It has been suggested that different mechanisms may be responsible for the development of mood disorders in fibromyalgia compared to other chronic pain conditions.

In particular, self-esteem has been linked to psychological adjustment in various chronic diseases (Chong et al, 2009), and how self-esteem is suspected to be a vulnerability factor in fibromyalgia (Johnson et al., 1997; Michielsen et al., 2006). Previous literature suggests that low self-esteem causes more negative affect for chronic disease patients than healthy populations (Bisschop et al., 2004). As self-esteem can be an important coping resource, one of the concerns raised by the combination of low self-esteem and chronic illness is an increased difficulty in preventing the negative affect from developing into a more severe case of depression. Research demonstrated that patients with chronic pain who had lower self-esteem reported more negative affect, less positive affect and greater symptom severity than individuals with higher self-esteem (Juth, Smyth, Santuzzi, 2008).

Despite the benefits of self-esteem, it has been suggested that high self-esteem is related to a number of negative outcomes including distortions in self-knowledge and increased aggression (Baumeister et al, 2003; Croker & Park, 2004). Reasons for this may be that self-esteem relies on meeting standards and favourable comparison with others (Neff, 2009). For this reason, research has started to focus on the construct of self-compassion which has been defined as the ability to be aware and open about one's flaws, while still being kind towards oneself.

Research on self-compassion is in its early stages, they have found that self-compassion is a significant predictor of increased psychological adjustment in people with chronic medical conditions (Wren, Somers, & Wright, 2011). Studies have also found that self-compassion correlates negatively with depression and anxiety (MacBeth & Gumley, 2012). It must be noted that much of the research on self-compassion has been conducted in non-clinical samples. Overall the literature appears to support the claim that self-compassion benefits people, especially when they experience failures or short comings. Research suggests that inclusion of positive and negative components of self-compassion would be beneficial in identifying

the 'active' components (Gilbert et al., 2011; van Dam et al., 2011). This study aims to investigate how self-compassion and self-esteem relate to pain outcomes in a chronic pain population, while also comparing their relative importance as mediators between pain intensity and outcomes of distress, disability and quality of life. It also aims to examine participants with fibromyalgia as a subgroup to investigate if there are differences within this population in relation to self-compassion and self-esteem as this group has been identified as having significantly high levels of distress and impaired functioning compared with other chronic pain patient groups (Gormsen, Rosenberg, Bach, & Jensen, 2010).

Research Question

Does self-compassion and self-esteem mediate between pain intensity and distress, functioning and quality of life?

How do the self-compassion subscales relate to pain outcomes?

Secondary Questions:

How does self-compassion and self-esteem relate to pain outcomes in a fibromyalgia subgroup compared to the overall chronic pain-group?

Study Sample

Individuals will be recruited through NHS Fife Pain Management Service, NHS Fife Rheumatic Diseases Unit and chronic pain support groups. All documents will each be marked with a unique participant number which will not identify the participant personally, ensuring their anonymity.

Patient Inclusion and Exclusion criteria:

Inclusion

* Must be at least 18 years of age

* Able to speak, read and write fluently in English

* Experienced chronic pain in any location of the body for a minimum of 3 months in line with the SIGN Guidelines (2013).

Exclusion

*Individual is suffering from malignant or terminal condition such as cancer.

*Individual has any of the below

-Intellectual impairment (e.g. Learning Disability, Alzheimers' Disease, Brain Injury)

-Severe mental illness

-Primary alcohol misuse

-Substance misuse

Number of participants

Given that no previous study has investigated the relationship between these variables in a chronic pain sample, the projected effect size for the current study has been conservatively estimated at a moderate level of $r^2 = 0.15$. Assuming a medium-size relationship between the predictors and the outcomes, $\alpha = .05$ and $\beta = .20$, the formula $N \geq 50 + 8m$ (where m is the number of predictors) can be used for testing the regression (Tabachnick & Fidell, 2007).

After calculating a G*power analysis, it was indicated that the minimum number of participants required for this study is 80. In order to carry out the appropriate statistics for this study with sufficient power, it is estimated that the required sample number is at least 120 participants.

Previous research has indicated that the response rate of postal survey studies among people with chronic pain range between 43-50% (Gunn et al., 2012). Given that the principal researcher aims to access up to 3 potential sources of recruitment, it is possible that at least 480 questionnaires could be circulated, which would guarantee the required sample size.

Consent Process

Participants will be recruited from NHS Fife Pain Management Service and the NHS Fife Rheumatoid Disease Unit. This will be a single site study in that participants will only be recruited the NHS Fife area. It is anticipated that the majority of participants will be identified by NHS Fife clinical staff (Clinical Psychology, Nurse Specialists) through their clinical role with participants. Clinicians will be asked to approach any patients they believe fulfil the inclusion/exclusion criteria and to provide them with the participant information and consent sheet. Potential participants will not be identified by any personal or clinical information.

Consent will be implied if the individual completes the questionnaires and posts them back to the address on the pre-paid envelope

Participant Withdrawal

The information provided by the participant for the research study will not be identifiable. Therefore, it will not be possible to remove their responses from the study after they have posted them back to the researcher. This will be made explicitly clear to the potential participants.

Procedure

Taking part in the study involves completing a number of questionnaires, which should take approximately thirty minutes to complete. The participant will also be asked to provide some very basic details e.g. gender, age, type of diagnosis which will not identify them personally. If they agree to take part in the study, they will be asked to post them back using the pre-paid envelope included.

Data collection

The study is a cross-sectional design. Attendees at the Fife Pain Management Service (NHS), the Rheumatic Disease Unit (NHS) and a voluntary sector chronic pain support groups (not affiliated with the NHS) will be recruited. They will be given a questionnaire pack that contains information sheets, a pre-paid stamped-addressed envelope and six validated questionnaires of pain, self-compassion, self-esteem, distress, disability and quality of life.

Permission has been granted by the primary authors for use of all of the questionnaires.

Self-Compassion Scale (SCS; Neff, 2003) is a 26 item scale that assesses levels of self-compassion. There are three factors of positive self-compassion: self-kindness, common humanity and mindfulness and three factors that focus on a lack of self-compassion and negative self-evaluation: self-judgement, isolation and over-identification. Participants indicate how often they engage in these ways of self-relating on a Likert scale 1-5. The scale has good reliability with Cronbach's alpha ranging from .72 to .83 (van Dam, Sheppard, Forsyth, & Earleywine, 2011).

Rosenberg Self Esteem Scale (RSES; Rosenberg, 1965) measures a global feeling of self-worth or self-acceptance. It is rated on a 4 point scale from 1, strongly agree to 4, strongly disagree. The ten statements are designed equally to be positive and negative. The total score ranges from 0 to 30. The scale has good reliability with a Cronbach's alpha of 0.89 (Michielsen, van Houdenhove, Leirs, Vandenbrock, & Onghena, 2006).

Brief Pain Inventory Short Form (BPI-SF; Cleeland, 1991) contains a total of 15 items and assesses for the presence of pain, pain intensity and functional interference from pain. It also catalogues the types of pain medications being used; the percentage of pain relief obtained from medications and assesses the distribution of pain via a body map. The BPI-SF is widely used in clinical trials for pain and is one of the instruments recommended by the initiative on methods measurement and pain assessment in clinical trials group (Dwarkin et al., 2005). Internal consistency for the Pain Severity Score and for the Interference scale has been reported as ranging from 0.85 and 0.88 respectively (jensen et al., 2004). Construct validity of the BPI has been supported for the generic assessment of pain as well as specifically for low back pain and rheumatoid arthritis (Keller at al., 2004).

Pain Disability Questionnaire (PDI; Anagnostis, Gatchel, & Mayer, 2004) incorporates a disability-related psychosocial component in addition to a physical functioning component related to pain. It yields a total functioning disability score ranging from 0 (optimal function) to 150 (total disability), using 11 point Likert scale (Gatchel et al., 2006). The PDQ has good reliability with a Cronbach's alpha of .96. The construct related validity of the PDQ was found to be excellent as it correlated well to both the MVAS (0.65-0.81) and Owestry (0.55-0.80) (Anagnostis et al, 2004).

Quality of Life Scale (QOLS; Burckhardt, Woods, Schultz, & Ziebarth, 2003) is a 16 item questionnaire that includes various aspects of life such as physical and material well-being, relationships with other people, social, community and civic activities, personal development and fulfilment, recreation and independence. Each item was scored 0-7 and the total score ranges 16-112. A higher total score shows a higher QOL. This scale has shown good internal consistency ($\alpha = 0.88$), validity and test-retest reliability (Pedro et al, 2014).

The Hospital Anxiety and Depression Scale (HADS; Zigmond and Snaith, 1983) is widely used for measuring anxiety and depression in clinical populations with physical illness. It contains 14 items and gives an overall measure of emotional distress as well as depression and anxiety subscale scores. It has shown good internal consistency ($\alpha = 0.90\text{-}0.93$), validity and test-retest reliability (Moorey et al., 1991; Snaith and Zigmond, 1994; Bjelland et al., 2002). In this study, a total score was used to represent emotional distress.

Table 1: Research Timescale

Feb	*Mar*	*Apr*	*May*	*Jun*	*Jul*	*Aug*	*Sep*	*Oct*	*Nov*	*Dec*	*Jan*	*Feb*	*Mar*	*Apr*	*May*
Ethics															
	Data Collection	*	*	*	*	*	*	*	*	*	*	End of Data Collection			
												Data Analysis			
													Write Up	Write Up	
															Submission

Analysis Plan

Preliminary analyses will be performed to check for missing data, normality and adequacy for mediation analysis. A set of bivariate Pearson's correlation analyses will explore the relations between the proposed mediators of pain and pain outcomes (distress, function and quality of life). Of additional interest will be to use multilpe regression to investigate the extent that the subscales of the SCS make individual contributions to predictive validity between pain and pain outcomes.

Multiple mediational analysis using the bootstrapping approach as described by Preacher and Hayes (2008) and Hayes (2009), will be used to investigate the relative importance that self-compassion and self-esteem have in the mediation of the relation between pain experiences (intensity) and pain outcomes (physical and emotional). To evaluate the magnitude of indirect effects, the product of co-efficients approach (Bishop, Fienberg, & Holland, 2008) will be used to calculate standard errors of the indirect effects.

To answer the second question of the study, a series of t-tests will be used to detect differences between the Chronic Pain and the Fibromyalgia.

Data Storage

All data will be stored in a manner consistent with NHS Fife guidance and policy on confidentiality and IT security, and in keeping with data protection legislation. Any of the data removed from NHS systems (e.g. for academic project work) will already be fully anonymised therefore, patient's anonymity will be preserved.

Publishing Outcomes

A report of the findings will be provided to Edinburgh University, the NHS Fife Psychology Department and submitted for publication in a peer reviewed journal.

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Appendix K-Ethical Approval Letters

South East Scotland REC 0
Waverley Gat
2 - 4 Waterloo Plac
Edinburg
EH1 3E

Telephone: 0131 465 547

26 March 2015

Ms Caitriona Doughty
Trainee Clinical Psychologist
NHS Fife
Lynebank Hospital
Halbeath Road
Dunfermline
KY11 4UW

Dear Ms Doughty

Study title: **The Role of Self Compassion and Self-Esteem in the Relationship between Chronic Pain and outcomes of Psychological Distress, Functioning, and Quality of Life**
REC reference: **15/SS/0035**
IRAS project ID: **147820**

Thank you for your letter of 24 March 2015. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 17 March 2015

Documents received

The documents received were as follows:

Document	*Version*	*Date*
IRAS Checklist XML [Checklist_24032015]		24 March 2015
Participant information sheet (PIS)	6	23 March 2015
Validated questionnaire [Brief Pain Inventory SF]	V2	23 March 2015
Validated questionnaire [Self Compassion Scale]	2	23 March 2015
Validated questionnaire [Pain Disability Questionnaire]	V3	26 March 2015
Validated questionnaire [Quality of Life]	V2	23 March 2015

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Non-validated questionnaire [caitriona doughty demographic questionnaire]		
Participant information sheet (PIS)	6	23 March 2015
REC Application Form [REC_Form_16022015]		16 February 2015
Research protocol or project proposal	Version 0.5	13 February 2015
Summary CV for Chief Investigator (CI)		
Summary CV for supervisor (student research)		
Validated questionnaire [Rosenberg Self Esteem Scale]		
Validated questionnaire [Hospital Anxiety and Depression Scale]		
Validated questionnaire [Brief Pain Inventory SF]	V2	23 March 2015
Validated questionnaire [Self Compassion Scale]	2	23 March 2015
Validated questionnaire [Pain Disability Questionnaire]	V3	26 March 2015
Validated questionnaire [Quality of Life]	V2	23 March 2015

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

15/SS/0035	**Please quote this number on all correspondence**

Yours sincerely

Sandra Wyllie
REC Manager

E-mail: sandra.wyllie@nhslothian.scot.nhs.uk

Copy to: *Ms Caitriona Doughty, NHS Fife*
Mrs Jo-Anne Robertson
Ms Aileen Yell, NHS Fife

Medical Director

Hayfield House
Hayfield Road
KIRKCALDY
KY2 5AH

NHS Fife

Ms Caitriona Doughty
Trainee Clinical Psychologist
Psychology Dept
Lynebank Hospital
DUNFERMLINE

31 March 2015
Our Ref *15-001 15/SS/0035*

Enquiries to *Aileen Yell*
E-mail *aileenyell@nhs.net*
Telephone *01383 623623 Ext 20940*
Website *www.nhsfife.org*

Dear Ms Doughty

Project Title: The role of self compassion and self-esteem in the relationship between chronic pain and outcomes of psychological distress, functioning and quality of life

Thank you for your application to carry out the above project. Your project documentation (detailed below) has been reviewed for resource and financial implications for NHS Fife and I am happy to inform you that NHS permission for the above research has been granted on the basis described in the application form, protocol and supporting documentation. The documents reviewed were:

Document	Version	Date
Protocol	0.5	13 February 2015
REC provisional favourable opinion letter		17 March 2015
Participant Information Sheet	6	23 March 2015
REC final favourable opinion letter		26 March 2015
IRAS R&D Form	3.5	27 March 2015
IRAS SSI Form	3.5	27 March 2015

The terms of the approval state that you are the Principal Investigator authorised to undertake this study within NHS Fife, with assistance from Jane Timperley in the Chronic Pain Management Team.

I note that the favourable ethical opinion applies to all NHS sites taking part in the study therefore no separate Site Specific Review is required in this case. The sponsors for this study are University of Edinburgh.

Details of our participation in studies will be included in annual returns we are expected to complete as part of our agreement with the Chief Scientist Office. Regular reports of the study require to be submitted. Your first report should be submitted to Dr A Wood, R&D Manager, R&D Department, Queen Margaret Hospital, Whitefield Rd, Dunfermline, KY12 OSU (Amanda.wood3@nhs.net) in 12 months time and subsequently at yearly intervals until the work is completed. A Lay Summary will also be required upon completion of the project.

In addition, approval is granted subject to the following conditions:-

All research activity must comply with the standards detailed in the Research Governance Framework for Health & Community Care (http://www.cso.scot.nhs.uk/publications/resgov/resgov.htm), health & safety regulations, data

NHS
Fife

protection principles, other appropriate statutory legislation and in accordance with Good Clinical Practice (GCP).

Any amendments which may subsequently be made to the study should also be notified to Aileen Yell, Research Governance Officer (aileenyell@nhs.net) , as well as the appropriate regulatory authorities. Notification should also be given of any new research team members post approval and/or any changes to the status of the project.

This organisation is required to monitor research to ensure compliance with the Research Governance Framework and other legal and regulatory requirements. This is achieved by random audit of research. You will be required to assist with and provide information in regard to monitoring and study outcomes (including providing recruitment figures to the R&D office as and when required). Please send a copy of all Monitoring Reports submitted to the REC to Allyson.bailey@nhs.net

As custodian of the information collated during this research project you are responsible for ensuring the security of all personal information collected in line with NHS Scotland IT Security Policies, until the destruction of this data.

Permission is only granted for the activities for which a favourable opinion has been given by the REC (and which have been authorised by the MHRA where appropriate).

The research sponsor or the Chief Investigator or local Principal Investigator at a research site may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety. The R&D office (aileenyell@nhs.net) should be notified that such measures have been taken. The notification should also include the reasons why the measures were taken and the plan for further action. The R&D office should be notified within the same time frame of notifying the REC and any other regulatory bodies.

I would like to wish you every success with your study and look forward to receiving a summary of the findings for dissemination once the project is complete.

Yours sincerely

DR BRIAN MONTGOMERY
Medical Director
NHS Fife

Cc : Aileen Yell, Research Governance Officer, NHS Fife, Queen Margaret Hospital, Dunfermline

University Hospitals Division

Queen's Medical Research Institute
47 Little France Crescent, Edinburgh, EH16 4TJ

FM/CK/approval

30 July 2015

Dr Evelyn Janetta
NHS Lothian
Pain Management Programme
Astley Ainslie Hospital
133 Grange Loan
Edinburgh
EH10 2HL

Research & Development
Room E1.12
Tel: 0131 242 3330

Email:
R&DOffice@nhslothian.scot.nhs.uk

Director: Professor David E Newby

Dear Dr Janetta

Lothian R&D Project No: 2015/0279

Title of Research: The role of self compassion and self-esteem in the relationship between chronic pain and outcomes of psychological distress, functioning and quality of life

REC No: 15/SS/0035

Participant Information Sheet:
Version 6.0, 20 March 2015

Consent Form:
N/A

Protocol: Version 5.0, 13 February 2015

I am pleased to inform you that this study has been approved for NHS Lothian and you may proceed with your research, subject to the conditions below. This letter provides Site Specific approval for NHS Lothian.

Please note that the NHS Lothian R&D Office must be informed if there are any changes to the study such as amendments to the protocol, recruitment, funding, personnel or resource input required of NHS Lothian.

Substantial amendments to the protocol will require approval from the ethics committee which approved your study and the MHRA where applicable.

Please inform this office when recruitment has closed and when the study has been completed.

I wish you every success with your study.

Yours sincerely

Fiona McArdle.

Ms Fiona McArdle
Deputy R&D Director

Cc: Dr Caroline Cochrane, Consultant Clinical Psychologist, Lead, Astley Ainslie Hospital
Ms Caitriona Doughty, Trainee Clinical Psychologist, Lynebank Hospital
Ms Jenny Fleming, General Manager, Western General Hospital

SCHOOL of HEALTH IN SOCIAL SCIENCE
CLINICAL AND HEALTH PSYCHOLOGY

The University of Edinburgh
Medical School
Doorway 6, Teviot Place
Edinburgh EH8 9AG

Telephone 0131 651 3969
Fax 0131 650 3891
Email submitting.ethics@ed.ac.uk

Caitriona Doughty
Trainee Clinical Psychologist
Dept of Psychology
Lynebank Hospital
Halbeath Road
Dunfermline
KY11 4UW

13 April 2016

Dear Caitriona,

Application for Level 1 Ethical Approval

Reference: CLIN266
Project Title: Self Compassion, Self Esteem and Chronic Pain
Academic Supervisors: Paul Morris / Nuno Ferreira

Thank you for submitting the above research project for review by the Department of Clinical and Health Psychology Ethics Research Panel. I can confirm that the submission has been independently reviewed and was approved on the 30th March 2016.

Should there be any change to the research protocol it is important that you alert us to this as this may necessitate further review.

Yours sincerely,

Kirsty Gardner
Administrator
Clinical Psychology

Appendix L- Participant Information Sheet

The relationship between self-compassion, self-esteem and pain in a chronic pain population

We would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. If you have any questions about this study not answered in this information sheet, you can contact the researcher, Caitríona Doughty.

What is the purpose of the study?

The purpose of the study is to improve understanding of the psychological factors (e.g. self-compassion and self-esteem) that contribute to the development of psychological distress and disability in chronic pain conditions. Clinical psychologists conduct research to contribute to the evidence about factors affecting mental health, in order to improve therapeutic approaches such as talking therapies. This study is being conducted as part fulfilment of the researcher's academic requirements of the Clinical Psychology Doctorate at University of Edinburgh. No one is being paid for your participation in this study.

Why have I been invited?

You have been contacted because you are an individual experiencing chronic pain for over 3 months, who has been attending any of the following service: NHS Fife Pain Management Service, NHS Fife Rheumatic Diseases Unit, Chronic Pain Self Management Group in Fife, NHS Lothian Pain Management Programme or NHS Lothian Rheumatology.

Do I have to take part?

No, you do not have to take part and you do not have to provide a reason. Your decision will not affect the standard of care or support you receive. You will be asked by a heath care provider or group facilitator if you would like a questionnaire pack for this study. If you agree to this, you can then take this home with you and decide whether you would like to participate. This study will be accepting response questionnaires from February 2015 to February 2016. **If you complete and return the attached questionnaires, this will be taken as your consent to participate.** Written consent is not being gathered in this study in order to maintain anonymity.

What am I being asked to do?

Taking part in this research involves completing a number of questionnaires, which should take approximately 35 minutes to complete. You will also be asked to provide some very basic details, which will not identify you personally in any way e.g. gender. If you agree to take part in this study you are asked **to post them back using the pre-paid envelope included**. This will be the only time information about you, or from you, will be required for this study and it will be the end of your participation in the study.

What are the possible disadvantages and risks of taking part?

The risks or disadvantages identified are minimal when taking part in this study. Completion of the questionnaires may be inconvenient and you may find some of the questions upsetting. You can stop completing the questionnaires at any time. You should speak to your GP if your distress continues. Listed below are a number of resources that you can access if you feel distressed. Included in this pack is a leaflet providing contact details for a confidential helpline service known as Breathing Space.

Moodcafe- The Well-being Website

Website Address: www.moodcafe.co.uk

Pain Association Scotland- Self Management for Chronic Pain

Contact telephone number: 0800 783 6059

What are the possible benefits of taking part?

While there are no direct benefits to taking part in this study, you may enjoy contributing to research that is intended to improve future patient care by providing a broader understanding of the factors that influence pain outcomes in a chronic pain population.

What if there is a problem?

If you have a concern or complaint about any aspect of this study, you should contact the researcher who will do her best to answer your questions (Caitríona Doughty, 01383 565402). If you would like to speak to an independent adviser who can answer questions about the study but is not directly involved in running the research you can contact - Tara Graham (Research & Service Development Psychologist), Department of Clinical Psychology Stratheden Hospital, Cupar, KY15 5RR. (01334 696336).

If you remain unhappy and wish to complain formally, you can contact Dr Katherine Cheshire, Head of Clinical Psychology Department, NHS Fife (01383 565403), or Paul Morris, Academic Tutor for the study (0131 6513956). You may also follow the NHS complaints route by contacting the Patient Relations Department office, Room 104, Hayfield House, Hayfield Road, Kirkcaldy, KY2 5AH, (01592 648153) or email patientrelations.fife@nhs.net.

What will happen if I don't want to carry on with the study?

The information you provide for the research study will not identify you. Therefore, once you have returned the questionnaires it will not be possible to remove your responses from the study should you change your mind.

Will my taking part in this study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. Information you provide for this study will not contain any personally identifiable information and therefore your participation will be confidential.

What will happen to the results of the research study?

A report of the findings will be provided to Edinburgh University, the NHS Fife Psychology Department and submitted for publication in a peer reviewed journal. If you require a copy of the report, please contact the researcher. Participants will not be identified in any way.

Who has reviewed the study?

The South East Scotland Research Ethics Committee 01, which has responsibility for scrutinising all proposals for medical research on humans in Tayside, has examined the proposal and has raised no objections from the point of view of medical ethics.

Thank you

Appendix M- Demographic Information Sheet

The Relationship Between Self-Compassion, Self-Esteem and Pain in a Chronic Pain Population

Demographic Information

Please answer the following questions

Recruitment site (researcher to complete prior to sending out packs)	
Gender	
Age	
How long have you experienced chronic pain	
Please list any diagnosis you have been given in relation to your chronic pain	
Was this diagnosis provided by your GP	**YES** ☐ **NO** ☐
Other, please specify	

Thank you.